UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

IN RE MYLAN N.V. SECURITIES LITIGATION	Master File No. 2:20-cv-00955-NR CLASS ACTION **Electronically Filed**

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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INTRODUCTION

This securities fraud case arises from Defendants' misrepresentation and concealment of Mylan's systemic and egregious violations of FDA regulations governing pharmaceutical product quality and safety—violations that the FDA told Mr. Malik directly were "stunning" and "egregious." Compliance with current good manufacturing practices or "CGMP" is fundamental to ensuring the safe and efficacious production of pharmaceutical products. Indeed, violations of CGMP by drug manufacturers like Mylan can lead to the production of adulterated drugs, fines, and penalties imposed by the FDA, and debilitating business disruptions. Needless to say, Mylan's compliance during the Class Period was of critical importance to investors.

Unbeknownst to investors, however, before the Class Period (February 16, 2016 through May 7, 2019), under Mr. Malik's direction, Mylan began to systematically disregard CGMP so that it could maximize production and, thus, Mylan's revenues. During the Class Period, the FDA documented non-public violations that were so widespread and serious that Mylan eventually halted production at its flagship facility in Morgantown, West Virginia, and admitted that massive increases in production had been undertaken at the expense of quality and safety measures. In fact, the underlying violations the FDA identified were themselves acts of fraud: systematic practices designed to hide failing drug test results. Throughout the Class Period, however, Mylan falsely and misleadingly touted their "stringent" quality control processes and rigorous product reviews, and minimized the significance of their regulatory violations.

There is a bedrock principle of federal securities law in the Third Circuit: "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."

Odeh v. Immunomedics, Inc., 2020 WL 4381924, *6 (D.N.J. July 31, 2020).[1] Thus, "a defendant may choose silence or speech based on the then-known factual basis, but cannot choose half-truths." *In re Bristol-Myers Squibb Sec. Litig.*, 2005 WL 2007004, at *23 (D.N.J. Aug. 17, 2005). Here, Defendants chose to speak. And with exacting particularity, the Complaint sets forth three categories of public misstatements by which Defendants sought to conceal Mylan's regulatory violations: (i) statements falsely promoting Mylan's quality assurance, adherence to CGMP regulations, and compliance with data integrity standards; (ii) statements misrepresenting and concealing the FDA's findings of CGMP violations at multiple Mylan facilities; and (iii) statements misrepresenting the scope and impact of remediation at Morgantown.

Substantiated by reports of FDA investigators, percipient and corroborative accounts of former Mylan employees, and the investigation of award-winning journalist, Katherine Eban, the Complaint exhaustively details why Defendants' Class Period statements were false or misleading when made. For example, the Complaint details critical safety violations, including how Mylan was illegally "testing into compliance"—that is, repeating laboratory analyses on failed drug samples until passing results were obtained. The Complaint further details how Mylan personnel: (i) crashed computers; (ii) shredded documents; (iii) altered test drugs; (iv) manipulated testing data; and (v) performed only a fraction of the testing mandated by FDA regulations, all to hide CGMP violations and avoid implementing costly remedial measures.

As they did during the Class Period, Defendants seek to minimize these CGMP violations, describing them here as "immaterial." But "testing into compliance" does not constitute a minor

[1] Unless otherwise noted: (i) capitalized terms have the same meanings as in the Consolidated Class Action Complaint (ECF No. 39); (ii) "¶__" refers to a paragraph in the Complaint; (iii) internal quotation marks and citations are omitted; (iv) internal alterations in the original are included; and (v) emphasis is added.

regulatory violation; it represents a concerted attempt to thwart oversight of a drug safety regime that demands thoroughness and investigation when drugs fail quality tests. Perhaps worse, Defendants argue that these critical quality and data integrity failures are "particularly immaterial in the case of large global manufacturers such as Mylan." This "too big to fraud" argument is without merit, particularly given that Mylan shut down its Morgantown facility in response to FDA findings of CGMP violations, which led to billions of dollars in remedial costs and lost business. As the FDA wrote to Mylan's executives, "[t]hese repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate."

Faced with these detailed allegations, Defendants seek to recast their obligation to speak truthfully into a single "question" of whether they had a "standalone duty" to disclose the FDA's findings documented in Form 483s. But that is not the legal standard where, as here, Defendants elected to speak affirmatively and repeatedly about quality controls and CGMP compliance. Once Defendants put those issues in play they were required to disclose all material facts belying their public statements, including the CGMP and data integrity violations plaguing Mylan's facilities.

Unable to contest the FDA's findings, Defendants attack the reports of numerous former Mylan employees, including two whistleblowers, and the comprehensive investigative reporting of Ms. Eban. This, too, fails. All of Plaintiff's sources are reliable and provide accounts of recurring regulatory violations at Mylan during the Class Period, are consistent with each other, and are corroborated by the FDA's findings. Nothing more is required at the pleading stage.

Nor can Defendants plausibly characterize the challenged statements as immaterial puffery or opinion. The statements alleged are replete with concrete, objectively verifiable assertions, often in response to analyst questions, and surely are not so unimportant to be immaterial as a matter of law. Numerous courts have upheld similar statements issued by pharmaceutical companies about

their adherence to critical safety regulations and operational standards. *See, e.g., In re Dr. Reddy's Lab. Ltd. Sec. Litig.*, 2019 WL 1299673 (D.N.J. Mar. 21, 2019).

Defendants' scienter challenges fare no better because the Complaint's allegations "taken collectively" raise a strong inference of scienter that is "at least as strong" as Defendants' proposed inference of non-culpable conduct. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 551 U.S. 308, 323 (2007). First, Defendants knew of and had access to information concerning the violations; in fact, the FDA regularly communicated with management through both in-person meetings and detailed correspondence, including an April 2017 meeting where the FDA personally informed Mr. Malik that Mylan's violations were "egregious." Second, the illegal nature and protracted duration of the misconduct, which exposed Mylan to penalties, remediation, and business disruption, is probative of scienter. Third, the repeat regulatory violations were the result of untenable production demands that sacrificed quality for quantity and were widely known throughout Mylan. Fourth, the violations endured for years at Mylan's "core operation" facility in Morgantown. Fifth, Defendants were motivated to conceal the truth to continue producing drugs at extreme volumes to stay ahead of competitors. These allegations are at least as compelling as any nonculpable inference Defendants seek to draw.

For the reasons discussed more fully below, Defendants' Motion should be denied.

STATEMENT OF FACTS

A. Pre-Class Period Events

Mylan is a generic drug manufacturer with its largest and most important facility located in Morgantown, West Virginia. ¶¶1-2, 31. Morgantown accounts for roughly 85% of the tablets and gel capsule drugs Mylan sold in the U.S. each year during the Class Period. ¶¶7, 34.

Mylan's success and reputation depended upon producing safe and efficacious products.

¶¶26, 35, 43. Mylan was required to comply with CGMP—stringent quality-control regulations promulgated by the FDA as the "main regulatory standard" to ensure safety and quality in drug manufacturing. ¶¶2, 44. CGMP regulations require drug manufacturers to establish strong quality management systems and robust operating procedures, to detect and investigate all product quality deviations, and to maintain reliable testing laboratories. ¶44. Indeed, under federal law, a drug is deemed "adulterated" when manufacturing processes do not conform to CGMP standards. ¶43.

In assessing compliance with CGMP regulations, the FDA relies on industry participants, like Mylan, to conduct testing and implement data quality controls to validate that testing, since the FDA cannot test all drugs distributed in the U.S. ¶¶44, 54. Because of this reliance, the FDA's data integrity requirements are a particularly critical component to ensure that test data is accurate, reliable, and uncorrupted throughout the CGMP data life cycle. ¶¶45-48, 54. Manufacturers are prohibited from re-testing drugs that have failed testing to achieve a passing result—i.e., "testing into compliance"—because doing so can conceal the production of unsafe drugs. ¶¶49-50.

Mylan and its executives, of course, were fully aware of the regulatory requirements pertaining to the manufacturing of pharmaceutical products. ¶56. Global consumers expected Mylan to abide by regulatory mandates and fastidiously monitor its drug manufacturing practices to ensure that its products reached the market safely, with the desired strength and purity. ¶43. Mylan itself recognized that "failure to comply with CGMP" could result in a host of serious regulatory sanctions and harm to its business, including "warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures," product recalls, and even criminal prosecution. ¶56. Simply put, Mylan's business, reputation, and ability to manufacture and sell its drugs depended on its strict compliance with CGMP and data integrity standards. ¶43.

Prior to the start of the Class Period, Mylan faced serious financial and competitive challenges. Specifically, low-cost, overseas manufacturers exerted significant pricing pressure on Mylan's generics business. ¶¶62-64. In response to this competitive threat, Mylan increased production to increase revenues. ¶¶65, 80-81. At the same time, Mylan represented to investors that in the "volume-driven" generic drug industry, Mylan could produce more drugs than its peers, while maintaining "operational excellence" and "stringent" quality standards, thereby differentiating itself from competitors. *E.g.*, ¶¶80, 271, 283, 289, 302-03, 307, 312. Unbeknownst to investors, however, Mylan's purported "strengths"—its ability to produce a high-volume, broad portfolio of drugs while maintaining strict quality and CGMP production standards—were illusory. ¶¶82-84, 281. Rather, to maintain production increases, Mylan's manufacturing facilities, including the flagship Morgantown facility, committed egregious CGMP and data integrity violations starting before the Class Period. ¶¶82, 85.

Conscientious employees were shocked by these systemic quality assurance failures. For example, in mid-2015, a whistleblower employee informed the FDA of "unscrupulous activity" at Morgantown and that Mylan's research and development center in Hyderabad, India had become a hub for data fraud, whose methods of data falsification had been disseminated throughout Mylan's India operations. ¶85. Among other things, the whistleblower reported that Mylan was: (i) "testing into compliance" by re-testing failed samples until passing results were obtained; (ii) switching commercial samples of specific drugs bound for the U.S. market with more stable pilot samples in order to generate passing product quality testing results; and (iii) concealing failed test results by deliberately corrupting data files and crashing computers when the instruments used for quality analysis began to indicate that an out-of-specification result was inevitable. ¶86.

The whistleblower reported that Mr. Malik's team instructed personnel to use these tactics to evade FDA investigators. *Id*. Other former Mylan employees provided similar reports of pre-Class Period misconduct, including about the illegal, widespread retesting of out-of-specification drugs and equipment until passing results were obtained. *See, e.g.*, ¶¶109, 111, 138.

According to multiple credible reports, by the start of the Class Period in February 2016, CGMP and data integrity violations at Mylan were systemic. *See* ¶¶109-29. Mylan's regulatory failures were the direct and deliberate result of its outsized production demands. *See* ¶¶130-44. Senior Mylan executives discussed that it was impossible for Morgantown to meet the facility's production requirements and to satisfy its CGMP compliance and product quality obligations. *See, e.g.,* ¶¶131, 133-34, 143. With the need for increased production, Mr. Malik purposefully under-budgeted quality control functions, including by gutting Morgantown's quality assurance teams. ¶¶132, 135. At Morgantown operations meetings, the "consistent drumbeat" was that, given the limited resources available to Morgantown and the complexity of the products, it was impossible to meet both production demands and product quality responsibilities. ¶133. Mylan's leadership set production schedules that left no time to correct problems. ¶140. According to one former Mylan employee, Morgantown's "astronomical" production volume "was not a cause, it was the cause" of the facility's CGMP failures, including pervasive "testing into compliance." ¶139.

B. The FDA Identifies Mylan's Widespread Quality Control And Data Integrity Failures At Morgantown And Nashik During The Class Period

In the latter half of 2016, as a result of repeated whistleblower complaints, FDA regulators identified and documented in Form 483s material safety and data failures at Mylan's facilities in Nashik and Morgantown. ¶¶91-107. At the Nashik plant, in September 2016, FDA investigators found evidence corroborating the whistleblower's report. ¶¶91-94. As a result, the FDA privately issued Mylan a lengthy Form 483 that documented unlawful practices of invalidating failing results

without sound scientific justification, and failing to investigate repeated software crashes and instead retesting drugs after receiving error messages. ¶¶52, 92-93. The findings confirmed the whistleblower and former employee accounts—Mylan had been committing data fraud to conceal non-compliant manufacturing processes. ¶93.

The FDA's inspection of Morgantown in November 2016 identified even more significant problems, including that Mylan was systematically using manipulative data practices to conceal failing quality control testing results that, if properly reported, could trigger lengthy production delays or product recalls. ¶¶95-107. For example, the FDA found thousands of random computer files containing what appeared to be forbidden exploratory tests, and bins full of shredded documents, including quality-control records, in areas where such documentation was to be preserved. ¶¶101, 103. As such, the FDA suspected Mylan had recorded passing scores on drugs that originally failed to meet quality standards. ¶104.

In response, on November 18, 2016, the FDA privately issued Mylan a 23-page Form 483 detailing its findings and conclusion that Mylan was impermissibly "testing into compliance." ¶97. In a separate letter, the FDA wrote that the inspections "raised questions regarding the integrity and reliability of data generated" by Mylan's quality control functions. ¶145. One former employee noted that, regarding the severity of the findings in the 2016 Form 483, "with that kind of report in this industry, the FDA would have been well within their right to deadbolt the door." ¶156.

The potential consequences for Mylan were enormous. Where the FDA discovers serious, pervasive, and repeat CGMP and data integrity violations, the FDA has the authority to order the manufacturer to take extensive remedial action that could necessitate the cessation of operations, implementation of costly, time-consuming remediation, and disruption of production. ¶53.

C. Defendants Fail To Remedy Quality And Data Failures At Morgantown And Conceal Data Integrity Issues

Investors knew nothing of the serious CGMP and data integrity issues that existed at Morgantown. *E.g.*, ¶¶181-82. To the contrary, Mylan falsely assured investors throughout the Class Period that, among other things, it "conduct[ed] reviews of all products, start to finish," used "advanced testing and monitoring systems to assure product adheres to testing acceptance criteria," and employed "advanced technology . . . to automatically remove a defective product from production or packaging lines." ¶¶67, 98, 254-55, 258, 260; *see also* ¶¶262, 264.

Meanwhile, CGMP and data integrity failures persisted at Mylan's facilities. On April 3, 2017, the FDA publicly issued Mylan a warning letter citing CGMP and data integrity violations at Nashik. ¶69. Like in prior inspections, the FDA warning letter stated that analysts at Nashik had improperly invalidated initial failing results of quality tests without adequate investigation, performed re-testing, and then reported the results of these replicate re-tests. ¶146. The FDA required Mylan to develop a remediation plan under the supervision of a consultant. *Id.*

In late-April 2017, Mr. Malik and six other senior executives met with FDA officials in an attempt to avert regulatory intervention directed at Morgantown. ¶150. FDA representatives told Mr. Malik they were "stunned" by Mylan's "egregious" violations, which they said led the agency to question whether the Company was being "transparent at all of its sites." *Id.* Given the seriousness of the violations, the FDA had already drafted a warning letter to issue to Mylan. ¶152. However, following intense lobbying by Mylan, the FDA agreed to downgrade its assessment to non-public criticisms. *Id*. Notwithstanding the FDA's scathing rebuke, Defendants continued to reassure investors that Mylan was dedicated to quality manufacturing across its plants and that all sites adhered to "stringent" quality standards. ¶¶281, 283; *see also* ¶¶146, 277, 286.

D. The FDA's March 2018 Inspection Of Morgantown Confirmed That Egregious Data Integrity Failures Remained Widespread

Defendants did not, however, properly remediate Morgantown because that would have resulted in a massive reduction of volume. ¶¶153, 161. Rather, Mylan made superficial changes designed to create the appearance of reform, including producing a "façade of documents" and backdating documents to suggest regulatory compliance that did not, in fact, exist. ¶¶154-60. Mylan's continued violations led to the recall of no less than fifteen different drugs at Morgantown. ¶162. Meanwhile, Defendants continued to assure the market that Mylan was complying with FDA regulations, including that Mylan was continuing to "manufacture tens of billions of doses of medicine annually, all to stringent quality standards." ¶283; *see also* ¶¶275, 279, 284.

On March 19, 2018, following receipt of a second whistleblower report that Mylan had created an "embedded culture" of fraud that had not been corrected, ¶154, the FDA returned to Morgantown for another surprise inspection—this time for four weeks—that resulted in another private and extensive Form 483. ¶164. The 2018 Form 483 cited the same egregious CGMP and data integrity violations about which the FDA had repeatedly warned Mylan's senior leadership, including in the 2016 Form 483. *See* ¶¶164-77. Just as it did in 2016, the FDA reported that Mylan's practice of "testing into compliance" was still widespread at Morgantown, finding that "[l]aboratory analyses are repeated until passing results are obtained." ¶¶165-67. The FDA excoriated "senior management" for failing to "ensure continuing suitability and effectiveness of quality systems through governance," and to correct what were "repeat violation[s]." ¶¶172-73.

Under intense regulatory pressure, Mylan finally relented. First, Mylan halted production at Morgantown while it attempted to remediate the CGMP and data integrity violations. ¶178. Second, Mylan dramatically reduced—by close to two-thirds—the massive production volume that had made it impossible to adequately perform mandatory quality control functions, including

thoroughly testing all drugs and investigating failing results. *Id*. Third, Mylan implemented remedial measures under consultant supervision and ensured those measures were validated and scalable before resuming production. *Id*. Additionally, Mylan recalled at least seven drugs manufactured at Morgantown, citing "CGMP violations." ¶180. Defendants withheld these facts from investors, however, and misleadingly stated that remediation "was not triggered just by this FDA inspection" but rather was part of a prior "plan" to "right size" Morgantown. ¶322.

E. The Relevant Truth Is Revealed And Mylan's Stock Plummets

The relevant truth about the FDA's inspections and Mylan's long-standing CGMP and data integrity failures began to partially surface in 2018. On June 27, 2018, *Bloomberg* reported that the FDA inspected Morgantown in 2018 and issued a Form 483 listing thirteen significant deficiencies in Morgantown's operations. ¶181. In response to the news, Mylan's share price fell approximately 3%, from $37.45 per share to $36.33 per share. ¶183. On August 8, 2018, during Mylan's first earnings call after the article, Mr. Malik downplayed the issues as "temporary," claiming that Mylan had planned the restructuring before receipt of the Form 483 and that Mylan would "re-bring volume back up" following the remediation. ¶187. Still, on this news, Mylan's stock price fell approximately 7%, from $39.23 per share to $36.61 per share. ¶188.

Meanwhile, the FDA continued to document pervasive CGMP and data integrity failures that had long existed at Mylan's facilities, and on November 9, 2018, the FDA issued a warning letter to Mylan and Ms. Bresch documenting widespread violations at Morgantown. ¶195. The warning letter "summarize[d] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals" that had been laid out in the April 2018 Form 483. *Id*.; *see also* ¶¶196-206. Furthermore, despite Defendants' public assurances during the Class Period that Mylan employed robust quality assurance processes that complied with "stringent quality standards," the warning letter stated, "[y]our firm lacks an adequate ongoing program for

monitoring process control to ensure stable manufacturing operations and consistent drug quality." ¶¶199, 281, 283. The FDA concluded in the warning letter: "These repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance." ¶203.

On February 26, 2019, Mylan released its financial results for the 2018 fourth quarter, disclosing a 5% decline of total quarterly revenues, a 16% decline for the quarter in North American segment net sales driven by the Morgantown remediation, the discontinuation of 250 products, and $258 million in remediation costs. ¶¶207-11. Mr. Malik assured investors that the negative impact from the Morgantown remediation was "largely behind us." ¶213. In response to this news, Mylan's share price fell $4.61 per share, or approximately 15%, from $30.62 per share to $26.01 per share, but analysts were encouraged by Mr. Malik's assurance that the worst was over. ¶¶212-16.

On May 7, 2019, Mylan reported a surprise loss for the first quarter of 2019 due, in significant part, to additional costs associated with the Morgantown restructuring. ¶217. On this news, Mylan's share price fell $6.73 per share, or approximately 24%, from $28.26 per share to $21.53 per share. ¶219. The news shocked market analysts, who noted that the Morgantown plant remediation continued to negatively impact the Company's financial results. ¶220.

ARGUMENT

I. LEGAL STANDARD

To state a claim under Section 10(b) of the Securities Exchange Act of 1934, plaintiffs must "allege defendants made a misstatement or an omission of material fact with scienter in connection with the purchase or the sale of a security upon which plaintiffs reasonably relied and plaintiff's reliance was the proximate cause of their injury." *Institutional Invs. Grp. v. Avaya, Inc.,*

564 F.3d 242, 251 (3d Cir. 2009). A court considering a motion to dismiss under the Private Securities Litigation Reform Act of 1995 ("PSLRA") should assess the complaint "in its entirety" and "holistically," accept all factual allegations as true, and construe the allegations in the light most favorable to plaintiffs. *Tellabs*, 551 U.S. at 322, 326. Factual disputes cannot be resolved on a motion to dismiss. *McGreal v. Westmoreland Cty*., 2020 WL 516309, at *2 (W.D. Pa. Jan. 28, 2020). Here, Defendants challenge two elements of Plaintiff's claim—falsity and scienter—and do not challenge the allegations related to proximate causation (or loss causation).

The Supreme Court "has long recognized that meritorious private actions to enforce federal antifraud securities laws are an essential supplement" to public enforcement brought by the U.S. Department of Justice or the SEC. *Tellabs*, 551 U.S. at 313. So has Congress. *See, e.g.*, S. Rep. No. 104-98, at 8 (1995) ("[P]rivate rights of action are not only fundamental to the success of our securities markets, they are an essential complement to the SEC's own enforcement program.") (quoting former SEC Chairman Arthur Levitt). Indeed, U.S. capital markets are the deepest and most liquid because "rules protecting investors are the most comprehensive and well enforced in the world." *See* Bhide, *Efficient Markets, Deficient Governance*, Harv. Bus. Rev., Nov.-Dec. 1994, at 130-31.

II. THE COMPLAINT ADEQUATELY ALLEGES MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

To plead a material misrepresentation under the PSLRA, a complaint need only allege facts "sufficient to support a reasonable belief as to the misleading nature of the statement or omission." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp*., 394 F.3d 126, 147 (3d Cir. 2004). Plaintiff alleges falsity if it specifies "the who, what, when, where, and how; the first paragraph of any newspaper story." *In re Providian Fin. Corp. Sec. Litig*., 152 F. Supp. 2d 814, 821 (E.D. Pa. 2001). A misstatement or omission is material if there is "a substantial likelihood that the disclosure of the

omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

Plaintiff alleges three categories of material misstatements and omissions regarding: (i) quality controls and assurance, compliance with CGMP regulations, and compliance with data integrity standards across Mylan's high-volume manufacturing model; (ii) the magnitude, nature, and severity of the FDA's findings regarding the Nashik and Morgantown facilities, as memorialized in Form 483s and in private conversations with Mr. Malik; and (iii) the magnitude and impact of remediation at the Morgantown facility. The Complaint alleges the falsity of each misstatement with exacting particularity. ¶¶254-325.

Defendants' primary challenge to falsity is that "the only question for the Court is whether Mylan was required to disclose the 2016 Form 483 and to disclose the Nashik Form 483 and 2018 Form 483 at earlier points in time." Defendants' Motion ("MTD") at 25. This misstates Plaintiff's case—which is broader than disclosure of the Form 483s—and well-settled falsity jurisprudence in this Circuit. As noted above, "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading." *Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017). "The law does not permit corporate executives to mislead investors through half-truths." *Roofer's Pension Fund v. Papa*, 2018 WL 3601229, at *13 (D.N.J. July 27, 2018).

A. Defendants' Statements Regarding Quality And Compliance Are Actionable

Throughout the Class Period, Defendants chose to speak affirmatively and repeatedly about Mylan's ability to mass-produce large volumes of safe and efficacious pharmaceutical products while maintaining "stringent" quality standards that met or "exceed[ed]" regulatory standards around the world. ¶¶67, 75, 281. These statements to investors were not one-off comments made in obscure documents—Defendants repeatedly pushed the statements to investors through a steady

stream of SEC filings, investor conference calls, social responsibility reports, published website announcements, media interviews, and a high-profile media tour of Morgantown itself. *E.g.*, ¶¶264, 267, 269, 277, 283. For example, during a May 10, 2017 conference call, Mr. Malik stated: "[w]ith regards to our operating platform, Mylan has always had a deep and unwavering commitment to quality everywhere we operate" and highlighted the Company's "deliberate and thorough approach to ensure sustainable quality across our entire network of facilities." ¶279.

Further, the Company's annual "Environmental, Social, and Governance Report" was replete with misleading statements about quality controls. Ms. Bresch stated in the 2017 Report that "[w]e are able to manufacture tens of billions of doses of medicine annually, all to stringent quality standards." ¶283. The Report also stated that manufacturing was "the most scrutinized area of any pharmaceutical company" and that Mylan had "invested significant resources to ensure quality throughout our value chain" and that "[e]ach of its steps is wrapped in a series of reviews designed to meet or exceed the many regulatory and compliance standards enforced by the dozens of health authorities around the globe that regularly inspect us." ¶284. Similarly, Ms. Bresch stated in the 2018 Report that "[f]or us, quality begins with product development, as we work to ensure an acceptable safety and efficacy profile for every drug we hope to market, and it extends through every step of the production process . . . ." ¶292. The 2018 Report also stated "[o]ur Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training." *Id*. The 2018 Report noted that "we have an extensive, formal internal-audit program to help monitor activity at our facilities" and that the Company had already performed 42 "quality and GMP audits at [its] own facilities." ¶¶292-93.

Throughout the Class Period, Mylan also devoted entire pages of its public website to

trumpeting its "quality" and compliance with CGMP standards, stating that Mylan "conduct[s] ongoing reviews to ensure quality and integrity of products, start to finish" and that each of its facilities, including Morgantown, "adheres to stringent quality standards, regardless of location." ¶¶256, 281; *see also* ¶254 (Mylan "applies one global quality standard across our facilities, and across our product line . . . regardless of market."); ¶279. Defendants also assured investors that Mylan's quality monitoring controls included "advanced testing and monitoring systems to assure product adheres to testing acceptance criteria." ¶258; *see also* ¶¶256, 260, 262, 267, 273, 288. Similar statements were made in media interviews. ¶277 (citing Mylan's "deliberate, thorough approach to assure sustainable quality across our entire network of facilities").

Defendants also touted Mylan's ability to mass produce a broader portfolio of drugs than its rivals, while still meeting or exceeding stringent quality and CGMP standards. Mylan's investor Proxy stated "[o]ur 50 plants around the world manufacture tens of billions of doses of medicines annually and each site adheres to stringent quality standards regardless of location." ¶281; *see also* ¶283; ¶303 (stating industry was "a volume-driven business, always" and Mylan could generate volume without sacrificing "the quality side of the house"); ¶271 (noting Mylan's "operational excellence and making almost 80% of everything we sell . . . [as] a real point of leverage"); ¶305 ("The need for a reliable supply is continuing to . . . . be a differentiator for Mylan.").

These statements were false and misleading. As detailed in the Complaint, Defendants concealed Mylan's serious and pervasive CGMP and data integrity violations, including at its most crucial Morgantown facility—practices that threatened Mylan's ability to sell pharmaceutical products altogether and undermined its professed high-volume advantage over rivals. The facts demonstrating falsity are based on numerous corroborating sources including: (i) formal FDA findings and communications in multiple Form 483s, warnings letters, and meetings with Mylan

executives; (ii) first-hand accounts of numerous former Mylan employees who witnessed inappropriate practices; (iii) facts and documents obtained in a comprehensive independent investigation by an award-winning journalist; and (iv) the Company's own admissions. ¶¶32-180.

Courts routinely find that such corroborative and interlocking sources render actionable statements touting pharmaceutical quality control and CGMP compliance. *See Dr. Reddy's,* 2019 WL 1299673, at *2-6, *9, *17 (finding actionable statements such as "[w]e take quality and compliance matters seriously and stand by our commitment to fully comply with the cGMP quality standards across all of our facilities" based on, in part, multiple Form 483s at multiple facilities and a warning letter citing "recurrent" and "long-standing" violations); *In re Able Labs. Sec. Litig*., 2008 WL 1967509, at *3, *16 (D.N.J. Mar. 24, 2008) (sustaining statements that the Company was "committed to [the FDA's [CGMP]] compliance," and "instituted operational procedures that enforce cGMP compliance" because "[t]he Form 483 and the warning letter provided notice to the defendants that serious problems existed in the manufacturing process"); *see also Wilkof v. Caraco Pharm. Labs., Ltd.*, 2010 WL 4184465, at *6 (E.D. Mich. Oct. 21, 2010) (quality statements actionable when "[t]he witnesses' claims of rampant manufacturing problems are consistent with the FDA's findings, including those detailed on" a Form 483 and in an "FDA warning letter").[2]

Likewise, where a company emphasizes "the strength of a particular business operation, [that] may be actionable as securities fraud, where those operations are in reality deficient." *Hall v. Johnson & Johnson*, 2019 WL 7207491, at *16 (D.N.J. Dec. 27, 2019) (statements that "quality

[2] *See also Todd v. STAAR Surgical Co.*, 2016 WL 6699284, at *6 (C.D. Cal. Apr. 12, 2016) (a company "may not lead its investors to believe that it is in compliance with FDA regulations while knowing that an FDA inspector concluded otherwise"); *Gov't of Guam Ret. Fund v. Invacare Corp*., 2014 WL 4064256, at *3-4 (N.D. Ohio Aug. 18, 2014) (finding statement that company "has assembled a team of internal quality and regulatory associates and outside experts to review the FDA's comments and recommend enhancements or improvements" actionable).

and safety, [is] our number-one priority" were actionable when "[t]he identified statements, and other similar attestations, [went] to the heart of Plaintiff's theory that the Company's quality assurance procedures were intentionally deficient, and that the Company deliberately avoided utilizing 'essential' testing which might reveal the existence of [the product's dangers]"); *see also City of Sterling Heights Gen. Emps.' Ret. Sys. v. Hospira, Inc.*, 2013 WL 566805, at *18-19, *23 (N.D. Ill. Feb. 13, 2013) (statements that company was "designed to . . . drive quality and operational excellence" and that its facilities were in "good operating condition" were actionable due concealment of regulatory violations stemming from company's strategy to "reduce" operating budgets and "slash" workforces especially at its facility generating 25 percent of revenues).[3]

1. The FDA's Findings Of Widespread Quality And Compliance Failures And CGMP Violations Reinforce Falsity

Contrary to Defendants' repeated representations touting Mylan's "stringent quality standards" and CGMP practices that "ensure quality and integrity of products, start to finish," the FDA discovered "egregious" CGMP violations at both Morgantown and Nashik. ¶96.

a. The FDA's Findings Of CGMP And Data Integrity Violations

Based on its first surprise eleven-day inspection of Morgantown in September 2016, the FDA documented the following failures during the Class Period:

- "Your firm manufactures drug products, <u>despite an awareness</u> of manufacturing investigation reports and complaints related to <u>known repeated</u> manufacturing deficiencies." Def. Ex. 1 at 10; ¶105.

[3] *See also Meyer v. Jinkosolar Holdings Co., Ltd.*, 761 F.3d 245, 251 (2d Cir. 2014) (finding statements that "pollution-preventing equipment and 24–hour monitoring teams" were actionable because they "gave comfort to investors that reasonably effective steps were being taken to comply with applicable environmental regulations"); *In re Equifax Inc. Sec. Litig.*, 357 F. Supp. 3d 1189, 1218-20 (N.D. Ga. 2019) (statements touting "highly sophisticated data information network" and "advanced security" were actionable where the plaintiff alleged "a variety of facts showing that [the company's] cybersecurity systems were outdated, below industry standards, and vulnerable to cyberattack, and that [the company] did not prioritize data security efforts").

- "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, adequate controls have not been instituted over electronic systems in your analytical laboratories" including "[b]atches are retested by analysts that may result in passing results being obtained." Def. Ex. 1 at 2-7; ¶¶98, 101.

- "Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards," "we found numerous documents in shredding bins," and noted "a trend of invalidating [out-of-specification] results due to an attribution to dirty glassware" and that the "trend had been previously identified and is an ongoing issue." Def. Ex. 1 at 7, 9-10; ¶¶99, 100, 102-03.

- "The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented" and certain "analysis" is "conducted using non-validated and non-verified analytical test methods." Def. Ex. 1 at 15; ¶104.

Following the inspection and issuance of the Form 483, the FDA informed Mylan by letter that its findings "raised questions regarding the integrity and reliability of data generated" by Mylan. ¶145.

In April 2017, Mr. Malik (and six other Mylan executives) met personally with the FDA to fend off further regulatory action. FDA representatives told Malik that they were "stunned" by the "egregious" violations, which led them to question whether Mylan was being "transparent at all of its sites." ¶150. FDA staff in two separate divisions concluded that the violations rated "Official Action Indicated" and the FDA had already drafted a warning letter for Morgantown. ¶152. But after an intense lobbying effort by Mylan, including Mr. Malik, an FDA attorney agreed to downgrade the rating—over strenuous staff objections—to keep the criticisms non-public. *Id*.

Later in 2018, after a Morgantown insider privately warned the FDA that, rather than addressing the "egregious" problems identified by the FDA, Mylan was creating a "façade of documents" to fend off the agency amid an "embedded culture" of fraud, the FDA launched a second surprise inspection of Morgantown and issued a second Form 483 in 2018. That 23-page document found that the same quality and CGMP failures had continued:

- "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity." Def. Ex. 2 at 14; ¶164.

- "Laboratory analyses are repeated until passing results are obtained." ¶¶165-67.

- "The responsibilities and procedures applicable to the quality control unit are not fully followed" including "numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow your procedure, *Organization of the Quality Unit*." Def. Ex. 2 at 2-3; ¶173.

- Mylan failed to properly "approve . . . validation protocols/reports for production processes, analytical methods or electronic systems that may impact the strength, quality, safety, efficacy, identity or purity of the finished drug product or API." Def. Ex. 2 at 3; ¶173.

- Mylan failed to "along with Senior Management . . . ensure continuing suitability and effectiveness of quality systems through governance including, but not limited to, Trending Review Board, Annual Product Review, Self-Inspection, and Quality Site Council." Def. Ex. 2 at 3; ¶229.

- "There are no written procedures for production and process controls designed to assure that the drug products have the identity strength, quality, and purity they purport or are represented to possess." Def. Ex. 2 at 19; ¶176.

- "There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed." Def. Ex. 2 at 27; ¶¶168-69.

- "Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed." Def. Ex. 2 at 31; ¶¶174-75.

The FDA's Morgantown warning letter confirmed that the failures set forth in prior Form 483s were severe, and repeated and "summarize[d] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals." ¶195. The FDA also reaffirmed that it had repeatedly warned the Company that its practice of "testing into compliance" was improper, noting that "the unjustified invalidation of failing test results is a repeat violation." ¶172. Moreover, the FDA stated that "[t]hese repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate" and

"[y]our executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance." ¶203. The FDA also noted that "[y]our firm lacks an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality." ¶199. The warning letter concluded, "[b]ecause your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of" federal law. ¶195.

The FDA also made clear that, due to repeat violations, Mylan's quality was suffering: "Your lack of rigorous oversight of manufacturing changes continues to be a major factor in the unexpected variation observed in your drug products." ¶201. The FDA emphasized that the CGMP and data integrity issues identified in the warning letter and the 2018 Form 483—including "invalidating numerous initial [out-of-specification] assay results without sufficient investigations to determine the root cause of the initial failure"—were "repeat violations at multiple sites." ¶202.

The warning letter also noted that the FDA previously "cited similar CGMP violations at [Morgantown] and other facilities in your company's network" referencing two warning letters in 2015 and 2017 focusing on Nashik and other facilities in India. Both of these prior letters warned Mylan about its "fail[ure] to thoroughly investigate unexplained discrepancies" and "invalidat[e]" numerous "initial out-of-specification assay results without sufficient investigation to determine the root cause of the initial failure." *Id*. Indeed, the Nashik Form 483 and warning letter cited similar CGMP violations as Morgantown, including "crashing files" to avoid failing test results, "invalidat[ing]" failing or out-of-specification results "without sound scientific justification," "invalidat[ing] . . . initial failing result[s]" of quality tests "without adequate investigation, perform[ing] re-testing, and then report[ing] the . . . results of these replicate re-tests." ¶¶69, 92-93. The agency also cited Mylan's failure to "thoroughly investigate any unexplained discrepancy

or failure of a batch or any of its components to meet any of its specifications." ¶146.[4]

b. Defendants' Unavailing Arguments Regarding FDA Findings

In response to these allegations of extensive and repeated regulatory violations, Defendants contend that the FDA's findings, as memorialized in the Form 483s and warning letters, were not sufficiently "material" to render Defendants' statements to investors misleading. MTD at 26-30. First, questions of materiality are classic factual issues as they depend on "the delicate assessments of the inferences a reasonable shareholder would draw from a given set of facts" and therefore "are peculiarly for the trier of fact." *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992). "Only if the alleged misrepresentations or omissions are so obviously unimportant to an investor that *reasonable minds cannot differ* on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Id*.

Second, Defendants misconstrue the Complaint by asserting that Form 483s are not "per se material" and did not represent quality violations that rendered any statements misleading. MTD at 26-27. But "the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading . . . depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 983-84 (8th Cir. 2012).

Here, the number, pervasiveness, and repeated nature of Mylan's violations indicate these findings would have been material to investors. *Cf. Okla. Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, 2020 WL 3268531, at *14 (S.D.N.Y. June 17, 2020) ("the seriousness of those

[4] Defendants' assertion that the Form 483s addressed different issues (MTD at 8-9) is incorrect—the findings all involve quality controls and CGMP compliance whether in laboratories or manufacturing. *E.g.*, ¶¶92, 99-101, 105, 164, 172, 175, 201, 203.

observations counsels in favor of holding that a reasonable investor could consider the letter akin to a warning letter"). For example, the Morgantown warning letter cited the pervasive failures documented in the Form 483s as "CGMP violations" that were "repeat violations at multiple sites." ¶202; ¶195 (stating that because Mylan's practices "do not conform to CGMP," its "drug products" were deemed "adulterated" under federal law). Moreover, the Morgantown warning letter expressly cited "similar CGMP violations" that the FDA had already documented in prior warning letters for multiple Mylan facilities as far back as 2015. ¶202. The FDA's findings alone, even before considering the reports of former Mylan employees and reports from independent investigative reporting, establish the materiality and falsity of the statements. *Dr. Reddy's*, 2019 WL 1299673, at *2-6; *Able Labs.*, 2008 WL 1967509, at *3, *16.

Further, Form 483s identifying falsification of testing data—like those here—constitute severe and pervasive conditions that must be disclosed to investors to avoid misleading investors about regulatory compliance. *See, e.g., Odeh*, 2020 WL 4381924, at *3 (statements actionable when Form 483 involved "personnel deliberately manipulating bioburden samples, deliberately misrepresenting test procedures in batch records and intentionally backdating batch records"); *Teligent*, 2020 WL 3268531, at *14 (statements actionable where Form 483 concerned "the validity and integrity of the studies conducted at [the Company's] study site."); *Able Labs.,* 2008 WL 1967509, at *2 (statements actionable where Form 483 involved "falsification of testing data and inaccurate reporting to the FDA"). Moreover, the violations here were of such severity that they caused significant business interruption and drug recalls. ¶¶178-80.

Third, Defendants' argument that Form 483s are never material when issued to "large manufacturers like Mylan" fails as the reported violations impacted a facility that accounted for 85 percent of oral and solid dose sales in the U.S.—by far Mylan's most significant business

segment. ¶7. Courts regularly sustain securities fraud complaints against large pharmaceutical manufacturers for misleading investors about quality assurance standards, CGMP compliance, and their impact on overall operations and manufacturing. *See, e.g.*, *Monk v. Johnson & Johnson*, 2011 WL 6339824, at *23 (D.N.J. Dec. 19, 2011) (multinational pharmaceutical company put "cost-cutting and quality assurance into 'play,' thereby creating a duty to disclose [the company's] general quality control deficiencies, the phantom recall, the other recalls").

Dr. Reddy's is instructive. There, like here, plaintiffs alleged misrepresentations regarding quality control and CGMP compliance such as "[w]e are fully dedicated to quality and have robust quality processes and systems in place at our . . . manufacturing facilities to ensure that every product is safe and of high quality" that the Company "maintain[s] a consistent global quality standard." *Dr. Reddy's*, 2019 WL 1299673, at *7-8. Likewise, plaintiffs there alleged misstatements seeking to downplay "the scope and severity" of the FDA findings as "pretty much a one site specific issue." *Id.* at *2, *4. The Court held that the statements were actionable based on allegations—like those here—that the defendants "ha[d] received two additional FDA Form 483s for two separate facilities" and that "significant pressure was put on the quality teams to cut corners and release batches of products from the review cycle without performing adequate quality assurance or control." *Id.* at *3-4. The court explained that defendants' statements "were in stark contrast to the allegation that the FDA subsequently discovered 'that serious cGMP violations still existed and in fact . . . that numerous items had not been corrected.'" *Id.* at *15.[5]

Other courts have sustained complaints based on similar CGMP compliance statements.

[5] Defendants' attempt to distinguish *Dr. Reddy's* and *Able Labs.* is unavailing. MTD at 30 n.13. Defendants' quality control statements here went beyond mere FDA "compliance" and stated that Mylan's "stringent" quality processes met or even "exceed[ed]" regulatory and compliance standards around the world. ¶¶67, 254, 256, 284-85.

See Odeh, 2020 WL 4381924, at *3-4, *6-7 (finding actionable statements regarding "potential receipt of a Form 483" and that company "may be subject to interruption" due to data integrity failures "[b]ecause a reasonable shareholder could consider the omitted information about the Data Integrity Breach and the Form 483 to be important"); *Invacare*, 2014 WL 4064256, at *3-6 (finding actionable statements that "[t]he company continues to strengthen its programs to better ensure compliance with applicable regulations" based on allegations of "numerous, pervasive and repeated violations of FDA and FDCA regulations," including statements by a former employee that "further confirmed that all of the issues identified in the Forms 483 and the warning letter . . . were legitimate, long-standing problems"); *Hospira*, 2013 WL 566805, at *18-19 (finding actionable statements touting "quality assurance," and "operational excellence" including that "facilities and equipment are in good operating condition and are well maintained" based on receipt of Form 483 and facts from former employees).

In contrast, Defendants' Form 483 case support does not address CGMP compliance statements at all. MTD at 26-30, 50, 56, 59-60. Instead, most of Defendants' cases address statements concerning new drug applications, where plaintiffs argued that findings of CGMP violations could endanger the application and should be disclosed—unlike here, where the CGMP violations directly contradicted multiple public statements concerning regulatory compliance and quality assurance. *See In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 130 (3d Cir. 2017) (statements about drug "approval" not actionable; FDA "never explicitly or even implicitly indicated" the facts that plaintiff alleged were omitted); *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42-43 (1st Cir. 2014) (statements regarding timing of FDA approval of the drug Lumizyme; Form 483 "made no mention of the Lumizyme approval process" and "bore no relation to FDA approval"); *Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *12 (S.D.N.Y. Apr. 28,

2020) (Form 483 did not contradict statements concerning NDA; but "the general weight of Form 483 cases across the country" finds statements concerning "substantial compliance with cGMP regulations" actionable in light of negative Form 483 findings); *Anderson v. Abbot Labs.*, 140 F. Supp. 2d 894, 905 (N.D. Ill. 2001), *aff'd sub nom. Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001) (alleged misleading statements "have nothing to do with quality control compliance").[6] Indeed, while the court in *McGuire* initially concluded that statements concerning a pending NDA were not rendered actionable by the issuance of a Form 483 alone (and the contents of the Form 483 were unknown), the court later sustained an actionable statement and concluded that the "receipt of the Form 483 is material" because "the disclosure of 'significant objectionable conditions' would significantly alter the total mix of information available to the reasonable investor." *McGuire v. Dendreon Corp.*, 2008 WL 5130042, at *5-6 (W.D. Wash. Dec. 5, 2008) ("Plaintiffs' allegations regarding the statement 'we hosted a good inspection, I think' are sufficiently well-plead as violations of Rules 10(b) and 10b-5 to survive a motion to dismiss.").[7]

Defendants' reliance on *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516 (W.D. Pa. 2019) (MTD at 17, 34-39) is equally unavailing. There, the alleged fraud was based on *Arconic*'s single sale of "wall cladding" to a third-party who installed the product unsafely in a building that caught fire. The court unremarkably found that statements in "product brochures" and filings regarding

[6] *Cf. Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 51, 53 (2d Cir. 1995) (MTD at 27-28) (statements concerning company's earnings potential not misleading where affected plant accounted for "less than 1% [of the company's] total sales"); *Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 239 (1st Cir. 2015) (MTD at 29) (statements involved "failing to attribute the growth in Impella revenues to unlawful off-label marketing practice").

[7] In *City of Pontiac General Employees' Retirement System v. Stryker Corp.*, 865 F. Supp. 2d 811 (W.D. Mich. 2012) (MTD at 28), the court held that the substance of the Form 483s—including handling of "patient complaints concern[ing] hip implants"—did not render any compliance misstatements misleading. *Id.* at 825. Indeed, the court found that the "generic" statements "did not refer to any particular investigation or facility" at all. *Id.* at 824.

"values and ethics" and general "safety" were not actionable, rejecting plaintiff's theory that "a failure to inform investors of this single sale to an end user who wound up using the product unsafely provides a basis for a securities law claim." 395 F. Supp. 3d at 535, 537, 541, 547-48.

Finally, Defendants' attempt, in a single footnote, to sweep in dozens of extrinsic documents and disputed "facts" found nowhere in the Complaint is inappropriate. MTD at 5 n.2. "As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings" and cited documents must be "*integral to or explicitly relied* upon in the complaint." *In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1426 (3d Cir. 1997). Indeed, "the unscrupulous use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery," a risk that is amplified in securities fraud litigation where "there is a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access." *Tomaszewski v. Trevena, Inc*., 482 F. Supp. 317, 329 (E.D. Pa. 2020). The Third Circuit has also admonished that the narrow exception for judicial notice "should be done sparingly at the pleading stage." *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007)

Defendants' brief offers the Court no justification for considering numerous extrinsic documents, including Exhibits 4, 5, 7, 10, 14-17, 30, and 35, which include technical interpretations of FDA and Irish regulations and other documents that are neither "incorporated" by reference into the Complaint nor "integral" to Plaintiff's claims. *U.S. ex rel. Sirls v. Kindred Healthcare, Inc*., 2021 WL 409981, at *5 (E.D. Pa. Feb. 5, 2021). Moreover, Defendants improperly seek to introduce many of their exhibits for the truth of matters asserted therein which

is inappropriate. *McCullough v. Advest, Inc*., 754 F. App'x 109, 111 (3d Cir. 2018) (per curiam).[8]

2. First-Hand Accounts Of Former Mylan Employees Reinforce Falsity

In addition to the FDA's findings, the material falsity of Defendants' Class Period statements is bolstered by the accounts of former Mylan employees (including whistleblowers who contacted the FDA) who witnessed improper practices at Morgantown before and throughout the Class Period.[9] Courts routinely credit particularized allegations from such sources in securities litigation. *Avaya*, 564 F.3d at 263; *Dr. Reddy's*, 2019 WL 1299673, at *2-6. The credibility of these accounts is further demonstrated by their corroboration with each other and their consistency with the FDA's own findings. *See Chubb*, 394 F.3d at 155 (noting "large number of varied sources may in some instances help provide particularity, as when the accounts supplied by the sources corroborate and reinforce one another").

For example, FE1, FE2, FE4, and FE5 reported, as the FDA did, that Morgantown repeatedly engaged in the improper practice of "testing into compliance." *Compare* ¶¶109, 111, 113-15 *with* ¶¶98, 165, 196 (FDA findings that "[l]aboratory analyses are repeated until passing

[8] For example, Defendants cite two FDA "closeout" letters (Def. Exs. 4, 7) for the proposition that Mylan "addressed the violations contained in" the Form 483s and warning letters. MTD at 6, 10. Neither letter is referenced in the Complaint and Defendants impermissibly offer the documents for their truth, and the implication that Mylan addressed the FDA's concerns after the Class Period has not been subject to examination. *Sturgeon v. Pharmerica Corp*., 438 F. Supp. 3d 246, 259 (E.D. Pa. 2020) (rejecting judicial notice of administrative guidance for its truth); *U.S. ex rel. Spay v. CVS Caremark Corp*., 913 F. Supp. 2d 125, 140 (E.D. Pa. 2012) (same). Likewise Defendants' request for judicial notice of a certification by an Irish agency (Def. Ex. 5)—following a one-day examination after six weeks' advance notice (Ex. A)—and an FDA guidance manual (Def. Ex. 14) is similarly improper and subject to factual disputes. As noted above, Defendants rely on exhibits that are not "undisputedly authentic" or "integral to or explicitly relied upon in the complaint," and thus should not be considered. *Hall*, 2019 WL 7207491, at *10. Nevertheless, if the Court is inclined to consider these exhibits, the Zivitz Declaration submitted herewith identifies and attaches responsive exhibits in the interest of completeness. *See* Exs. A-F; *see also* pp. 32-33 n.12.

[9] Plaintiff refers to the Mylan employees it interviewed as "Former Employees" or "FEs" to preserve their anonymity. ¶95 n.4. This is an accepted practice in securities litigation as "there is no reason to inflict the obligation of naming confidential sources." *Chubb*, 394 F.3d at 147.

results are obtained"). FE3 and FE5 each reported, as the FDA did, that Morgantown had a practice of improperly invalidating failing test results, which enabled technicians to disregard failing samples in determining whether a batch had passing data. *Compare* ¶¶112, 115, 128 *with* ¶¶92, 99, 145, 166, 170, 172, 202 (FDA findings of "unjustified invalidation of failing test results"). FE1 and FE2 reported, as the FDA did, that Mylan engaged in the practice of scrubbing data and "crashing files" to cover up negative results. *Compare* ¶118 (widespread practice of "crashing files") *with* ¶¶93, 103 (shredding documents and "crashing files" to ensure failing data was not retained).

Moreover, the FEs confirm that the pervasive failures and violations set forth in the FDA Form 483s and warning letters existed prior to and throughout the Class Period, including in 2015. *See, e.g.*, ¶110 (FE1 confirming that "testing into compliance" and failure to test vast majority of manufactured drugs occurred in 2015 and 2016, prior to the FDA's Form 483s); ¶¶113-14, 117 (FE4 reporting that "testing into compliance" occurred at Morgantown "throughout his tenure," which commenced before the Class Period); ¶115 (FE5 reporting that failing tests were re-tested without adequate investigation at numerous Mylan sites, including Morgantown, Nashik, and Bangalore prior to November 2016); ¶¶132-33, 157 (FE6 reporting based on production meetings in 2014 and 2015 that it was impossible to meet both the facility's production demands and its product quality responsibilities); ¶143 (FE7 reporting based on three meetings between the end of 2015 and November 2016 that Mylan's Head of OSD Site Operations at Morgantown stated that the volume and pace of production was causing significant CGMP compliance problems).

Furthermore, FE2, FE3, FE4, FE6, and FE7 each reported that Mylan's relentless pursuit of high-volume manufacturing caused widespread quality and data integrity problems. *Compare* ¶¶113, 122, 132, 137, 139, 143 *with* ¶¶100, 103, 105, 166, 168, 171, 173 (FDA findings of practices

including "numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow" Mylan's own procedures). Mylan admitted in private correspondence with the FDA following the 2018 Morgantown inspection that "the large volume of doses and products within the Morgantown portfolio . . . inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect." ¶177. These detailed allegations from multiple corroborating sources are sufficient to state a claim. *See Dr. Reddy's*, 2019 WL 1299673, at *2-6; *Able Labs.*, 2008 WL 1967509, at *2, *7, *9; *Invacare*, 2014 WL 4064256, at *6.[10]

The FE accounts are additionally reliable because Plaintiff has "described the duration of each [FE]'s employment, the time period during which the [FEs] acquired the relevant information, and how each [FE] had access to such information." *Avaya*, 564 F.3d at 263. Specifically, Plaintiff demonstrates that each FE was employed by Mylan for the entirety or a substantial portion of the Class Period, provides their job descriptions and responsibilities, and shows that each FE's account reflects particular facts plausibly obtained within the scope of their respective positions. *E.g.*, ¶¶95, 111-15, 131. The FE accounts are also mutually consistent. *E.g.*, ¶¶111-15. This is all that is required. *See, e.g., Pelletier v. Endo Int'l plc*, 439 F. Supp. 3d 450, 468 n.8 (E.D. Pa. 2020) ("the key [FE] allegations are specific, mutually consistent, and plausibly within the scope of knowledge

[10] Defendants' assertion that Plaintiff cannot dispute certain threshold "facts" is incorrect. MTD at 24-25. First, whether the "allegedly objectionable conditions" in one (but not both) of the Morgantown Form 483s "did not meet the threshold of regulatory significance" is a disputed issue of materiality. *See* § II.A.5. Second, whether the "Irish equivalent" of the FDA "certified" Morgantown as "compliant" is subject to disputes regarding, in part, the meaning of "certified" and "compliant" under Irish regulations and the materiality of those "facts." It is also irrelevant as the fraud here has nothing to do with Irish standards. Mylan is a U.S.-based company, trading on a U.S. exchange, subject to FDA jurisdiction, with its most important facility in West Virginia. Third, Plaintiff does, in fact, dispute whether Mylan "promptly" disclosed the two warning letters. *See* § II.C. Fourth, whether Mylan appropriately disclosed the Nashik Form 483 "after" the issuance of the Nashik warning letter, or "acknowledged" the Morgantown 2018 Form 483 "within two months" of issuance, is part of the core factual disputes underlying Plaintiff's claims that Defendants' statements misled investors and concealed material facts.

each [FE] would have acquired during his or her employment").

Defendants' challenges fail. First, Defendants wrongly argue that "Plaintiff's attempt to characterize [the FDA findings] as 'widespread' or 'egregious' . . . relies entirely on unsupported hyperbole from anonymous sources." MTD at 12. The FEs substantiate other well-pled facts, including a substantial record of FDA action and Mylan's own subsequent admissions and remedial measures. *See* ¶203 (FDA warning letter: "These repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacturing of drugs is inadequate."); ¶14 (Mylan admitting that its high-volume model had "inhibited" its ability to "control" manufacturing); ¶¶178-80, 185-87 (remedial measures including halting production at Morgantown, recalling or reducing generic drugs, and increasing operating costs).

Second, courts routinely reject Defendants' argument the FEs should be disregarded as "low-level." MTD at 12. *Avaya,* 564 F.3d at 265-66 (crediting "relatively low-level former employees"); *Lord Abbett Affiliated Fund, Inc. v. Navient Corp.*, 363 F. Supp. 3d 476, 493 (D. Del. 2019) (rejecting argument that "the CWs' allegations should be steeply discounted, because they are 'all low-level former employees' and 'were not employed for the full class period'").

Third, Defendants' claim that that some of the FEs were not employed through the entirety of the Class Period (MTD at 13) is similarly unavailing as each recounts first-hand observations based on experiences while they were Mylan employees. Nowhere does the Complaint rely upon rumors or speculation. Fourth, Defendants' argument that the FE's do not claim to have performed particular laboratory procedures is irrelevant. MTD at 14. Each of the FE's Defendants challenge are Mylan chemists (FE3 and FE4) and quality control personnel (FE1 and FE5) who reliably reported improper lab procedures based upon their personal experiences. Moreover, their allegations are consistent with the findings of the FDA at Morgantown in the 2016 and 2018 Form

483s.

Fifth, Defendants' individual attacks on the FEs fare no better. For example, Defendants criticize FE1's statements as failing to allege personal knowledge and being "untethered in time." In fact, the Complaint makes clear that FE1 described events that FE1 perceived; indeed, there are multiple instances where FE1's statements indicate personal knowledge and utilize the first person. ¶109 ("I can't ever remember doing that at Mylan"); ¶110 (FE1 "reported these issues to senior Mylan executives"); ¶120 ("I saw people scratch out the .1 and add two 0's so you get at 10.00"). Moreover, FE1's allegations are amply tethered in time. *See, e.g.,* ¶¶109, 116, 125-26. Similarly, Defendants attack FE2 as offering "vague and generalized" allegations regarding the retesting of samples with OOS results. But FE2, who was "responsible for analyzing drugs and equipment for compliance with quality standards," recounts how he was personally instructed by superiors to retest samples until they passed—the exact same failure identified repeatedly by the FDA. ¶111.

Finally, the Court should disregard Defendants' allegation that Plaintiff "misuse[d] or mischaracterize[ed]" interview statements, which reflects their objection to the term "testing into compliance" (MTD at 19), a common industry phrase that is used in FDA guidance. ¶¶109-14, 136-37, 139, 241. Regardless, this is, in effect, an attack on the truth of Plaintiff's well-pled allegations, which is not permitted at the pleading stage. *Tellabs*, 551 U.S. at 326.

3. Other Secondary Sources Are Reliable

Plaintiff also incorporates detailed facts from *Bloomberg* and *Bottle of Lies*, an investigative book based on Ms. Eban's decade of reporting on the generic drug industry. Media sources are well-accepted when they are sufficiently detailed to indicate reliability and "based on an independent investigative effort." *In re Loewen Grp. Inc.,* 2004 WL 1853137, at *6 (E.D. Pa. Aug. 18, 2004). Both sources meet this standard.

First, Ms. Eban's *Bottle of Lies* represents an exhaustive "independent investigative effort"

by an award-winning journalist and Rhodes Scholar. The book has been widely praised.[11] Ms. Eban "obtained a significant number of confidential documents" including "roughly 20,000 internal documents from the [FDA], including emails, memorandum, meeting minutes, reports, and data[.]" Def. Ex. 33 at 4. Ms. Eban notes she "interviewed over 240 people, a number of them multiple times, including regulators, drug investigators, criminal investigators, criminal investigators, diplomats, prosecutors, scientists, lawyers, public-health experts, doctors, patients, company executives, consultants, and whistleblowers." *Id.*

Second, Ms. Eban's reporting is also sufficiently detailed to indicate its reliability. For example, Plaintiff cited Ms. Eban's investigative reporting regarding confidential Mylan records relating to the 2015 and 2016 FDA whistleblower reports, and Mylan's correspondence with the FDA in 2016 and 2017. ¶¶89, 91. Ms. Eban's reporting on these subjects is detailed and based in part on her personal review of documents and her interviews of those involved. Def. Ex. 33 at 19-21; *see* ¶¶85-88, 150. Similarly, Ms. Eban's reporting of Mylan's reaction to the 2016 Form 483 is based on her review of Mylan's "meetings, calls, and correspondence with the FDA," including a January 2017 "lengthy, confidential letter" that Eban quotes directly. Def. Ex. 33 at 22.

Defendants incorrectly assert that Plaintiff cannot rely on witnesses quoted in *Bottle of Lies* and *Bloomberg*. *In re Lehman Bros. Sec. & Erisa Litig.*, 2013 WL 3989066, at *4 (S.D.N.Y. July

[11] In awarding *Bottle of Lies* the Cornelius Ryan Award for best non-fiction book on International Affairs, the Overseas Press Club called it a "shocking and masterful work of global investigative reporting" Ex. B. *The New York Times* called *Bottle of Lies* "an invaluable exposé, a reportorial tour de force." Ex. C. *The Yale Journal of Biology and Medicine* wrote that *Bottle of Lies* "addresses issues that may not be widely known, even among healthcare professionals, and serves as an important impetus for readers to be critical of the medications they take and brings awareness to the inequities faced by patients in countries with less regulatory power." Ex. D. Daniel J. Kevles, Professor of History Emeritus at Yale, in a review in *The New York Review of Books*, wrote that "*Bottle of Lies* reminds one of the investigations of corporate America and its products by journalists and scientists at the turn of the twentieth century that led to several powerful reforms." Ex. E. *Foreign Affairs* likewise called *Bottle of Lies* a "detailed investigation." Ex. F.

31, 2013) ("a plaintiff may rely in its complaint on witness statements recounted in newspaper articles and government reports") (MTD at 19). Here, these sources are sufficiently particular and detailed to establish their reliability, including specifying the time period of the events discussed by the witness. This is in contrast to *Chan*, (MTD at 22), where the contested article simply quoted former and current employees, but did not establish whether those quotations referred to events occurring during the class period. *Chan v. New Oriental Educ. & Tech. Grp. Inc.*, 2019 WL 2865452, at *3, *7 (D.N.J. July 3, 2019). In any event, much of Ms. Eban's reporting relies on first-hand review of documents—not interviews with unnamed witnesses.

Tellingly, rather than challenge the rigor of Ms. Eban's reporting, Defendants instead append a *Washington Post* book review to try to undermine its reliability. MTD at 19, 21. Far from impugning the quality of Ms. Eban's investigation as Defendants claim, the review praises both Ms. Eban and the thoroughness with which *Bottle of Lies* was researched, lauding the book for "expos[ing] corruption and deception at the highest levels of one of India's largest exporters of generic drugs" and "reveal[ing] the thinning edge of U.S. regulatory power in a rapidly globalizing pharmaceutical industry." Def. Ex. 35 at 2-3. While Defendants highlight the reviewer's characterization of the book as "lopsided," in reality the review states that the book "paints an uneven picture for readers," because "the willingness of pharmaceutical companies to promote substandard and potentially harmful agents. . . can be found just as readily among European and North American brand-name manufacturers." *Id.* Accordingly, the reviewer suggests that, if anything, Eban understated the risk posed by U.S. generic manufacturing operations, just like Morgantown. Likewise, Defendants put forth no specific argument as to why the *Bloomberg* articles are unreliable. Nor could they. *Bloomberg* is a highly reputable source and the articles reflect independent investigation while recounting details from FDA documents. ¶¶85, 144.

4. Mylan's Website And Other Corporate Statements Are Actionable

Defendants' wrongly assert that the statements on Mylan's website, press releases, ESG Reports, and certain articles cannot be actionable—even if demonstrably false—simply because they were not specifically attributed to an individual executive. MTD at 47 n.26 (citing statements ¶¶254, 256, 258, 260, 262, 264). First, Defendants do not and cannot dispute that these statements are directly attributable to at least one Defendant—Mylan itself. This renders them actionable. *See, e.g.*, *In re Rocket Fuel, Inc. Sec. Litig.*, 2015 WL 9311921, at *7 (N.D. Cal. Dec. 23, 2015) ("the court finds that plaintiffs have adequately alleged that the . . . website posting are false or misleading"); *Invacare*, 2014 WL 4064256, at *9 (finding actionable "statements . . . on the Company website [that] downplayed and obscured the serious, pervasive nature of Invacare's FDA violations"). Indeed, "it is reasonable for companies maintaining websites to anticipate that current or potential investors might read and rely on website statements." *Last Atlantis Cap. LLC v. AGS Specialist Partners*, 749 F. Supp. 2d 828, 834 (N.D. Ill. 2010).[12]

Second, in SEC filings signed by the Defendants and during investor conferences, Mylan repeatedly encouraged investors to visit its website to better understand its business. ¶67. Third, the website statements are virtually identical to Defendants' own statements in investor calls, SEC filings and other investor reports, further evidencing Defendants' endorsement and authority over the statements. *Tomaszewski*, 482 F. Supp. at 335. Fourth, Defendants' separate argument that Plaintiff has not alleged "corporate scienter" for those statements is incorrect. *See* § III.G.

[12] *See also SEC v. Enters. Sols., Inc.*, 142 F. Supp. 2d 561, 577 (S.D.N.Y. 2001) (holding that company website statements that it "developed a suite of products" and "established business relationships with customers that will last a lifetime" were actionable); *SEC v. Stinson*, 2011 WL 2462038, at *5 (E.D. Pa. June 20, 2011) (finding that statements in "various web sites" were "made to induce investors to purchase and retain their securities").

5. Defendants' Quality Statements Are Not Puffery

Defendants ask this Court to rule as a matter of law that certain statements are inactionable puffery or vague statements of optimism. MTD at 33-39. These are context-specific, fact-based defenses to materiality that "are peculiarly for the trier of fact." *Shapiro*, 964 F.2d at 280 n.11 (dismissal on materiality grounds only permitted if information is "so obviously unimportant to an investor that *reasonable minds cannot differ* on the question of materiality") (italics in original).

Here, "[b]y placing the nature of the Company's quality assurance procedures 'in play,' Defendants were also required to disclose 'certain facts contradicting th[ose] representations.'" *Hall*, 2019 WL 7207491, at *16. Moreover, Defendants' statements regarding Mylan's "stringent" quality standards and CGMP practices across all of its facilities, including Morgantown, were concrete and objectively verifiable. *Wilkof*, 2010 WL 4184465, at *2, *4 (statement that company was "substantially cGMP compliant" was an issue "subject to objective verification"); *Dr. Reddy's*, 2019 WL 1299673, at *17 (same); *Hospira,* 2013 WL 566805, at *23 (statements that company "believes that its facilities and equipment are in good operating condition and are well maintained" not puffery when it had received FDA findings of "quality-control issues"); *Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 968 (N.D. Cal. 2014) (statements that company was "commit[ed] to providing the highest quality products to our customers" were "not so 'obviously unimportant'" given company's role in "an industry where regulatory compliance, not to mention consistency and sanitation in production, is essential").[13]

[13] Defendants fail to cite a case where a company, as here, touted the strength of a particular business practice and instead rely on inapposite cases involving generic assertions. MTD at 36; *Singh v. Cigna Corp.*, 918 F.3d 57, 64 (2d Cir. 2019) ("simple and generic assertions about having 'policies and procedures' and allocating 'significant resources'"); *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1321 (11th Cir. 2019) ("vague statements about its efforts towards compliance"); *Emps. Ret. Sys. of the State of Haw. v. Whole Foods Mkt., Inc.*, 905 F.3d 892, 902 (5th Cir. 2018) ("generalized statements about [the company's] transparency, quality, and responsibility"); *Howard*, 395 F. Supp. 3d at 547 ("general" statements about "values, workplace safety, and

Furthermore, when Mylan's quality and CGMP problems—and their adverse impact on Mylan's performance—were partially revealed in 2018 and 2019, Mylan's stock declined sharply on the news, further evidencing the importance of the concealed information. *Able Labs.*, 2008 WL 1967509, at *15 ("the significant decrease in stock price immediately following the disclosure of the adverse information satisfies the Third Circuit's standard for pleading materiality"); *In re Par Pharm. Sec. Litig.*, 2009 WL 3234273, at *10 (D.N.J. Sept. 30, 2009) (same).[14]

6. Defendants' Quality Statements Are Not Nonactionable Opinions

An opinion statement is actionable either (i) if the opinion was not sincerely held or (ii) even if it was, if the statement "omits material facts about the issuer's inquiry into or knowledge concerning [the] statement," and the omitted facts show that the speaker "lacked the basis for making those statements that a reasonable investor would expect." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189, 196 (2015). Many of the statements Defendants cite—e.g., ¶¶302-04, 306-09, 311-12, 314, 319—are not opinions, but are direct and concrete assertions of fact. *See, e.g.*, ¶314 (referencing Morgantown: "we're running facilities that are making 15 billion tablets and capsules in a year"); ¶307 (citing Mylan's "ability to be that reliable supplier with the capacity to do the kind of the volumes that need to be done across these products"). Thus, *Omnicare* does not apply. *In re Merck & Co., Inc., Sec. Litig.*, 2015 WL 2250472, at *11 n.7 (D.N.J. May 13, 2015) (*Omnicare* inapplicable where statements "ma[de] direct assertions" instead of "express[ing] Defendants' opinion or belief in some assertion").

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ethics—which read like mission statements rather than guarantees"). Nevertheless, Defendants gloss over certain material statements similar to those alleged here. MTD at 37-38; *Martin v. GNC Holdings, Inc.*, 2017 WL 3974002, at *10 (W.D. Pa. Sept. 8, 2017) (finding statement "[r]egarding regulatory risk" that "[w]e know how to manage it" was material).

[14] Defendants' speculation that "if" the conduct was pervasive, the FDA "would have seized Mylan's products or sought an injunction and/or other available sanctions" (MTD at 25 n.11) is cannot be credited at the pleading stage. Moreover, the Complaint alleges that many of the CGMP and data manipulations were designed to evade FDA detection. *E.g.*, ¶¶6, 86, 99, 119, 166.

Even if the statements are treated as opinions, they are still actionable because there existed no reasonable basis for those opinions and the statements omit then-existing facts regarding the systemic quality and data integrity failures and violations throughout the Class Period. ¶¶267, 273, 288. Moreover, Defendants' statements about their competitive advantages, including their ability to maintain a high-volume, high-quality model, are also actionable because they omitted material facts as to how Mylan had achieved this advantage; that is, by violating CGMP, data integrity and quality compliance measures to meet volume demands. *Payne v. DeLuca*, 433 F. Supp. 2d 547, 562 (W.D. Pa. 2006) ("[G]eneral statements of optimism" may be actionable when made by "top corporate officials . . . [and] made without a reasonable basis."); *In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357, 368 (3d Cir. 1993) (same); *see also Invacare*, 2014 WL 6982233, at *4 ("merely because Defendants couch some of their statements with terms like 'our belief' or 'we believe' or 'our highest priority' or 'in my opinion,' the Court is not swayed."). Defendants' contention that their statements did not necessarily implicate Morgantown (MTD at 43) ignores that Morgantown manufactured roughly 85% of the oral solid doses Mylan sold in the U.S. during the Class Period. ¶7. Indeed, after initiating remediation at Morgantown, Mylan attributed the 22% decline in North America revenue, in part, to "the impact of the restructuring and remediation program in our Morgantown manufacturing facility." ¶¶186, 194.

B. Defendants' Statements After The FDA's Surprise Inspections Concealing The True Magnitude And Impact Of The Regulatory Compliance Failures

Defendants also misled investors by misrepresenting Mylan's compliance with FDA regulations following receipt of the Form 483s, *see* ¶¶273, 275, 279, 288-90, 292-93, 295, and for statements about the Nashik remediation. ¶¶277, 286.

1. Defendants' Failure To Disclose The FDA's Express Criticisms Rendered Their 2017 And 2018 Statements Misleading

Defendants' statements regarding Mylan's quality and manufacturing made after receiving

the Form 483s and private criticisms by the FDA were materially misleading by omission. Defendants' issuance of Mylan's Form 10-Ks (filed on March 1, 2017 and March 1, 2018), and Form 10-Q (filed on May 10, 2018) misleadingly represented that any regulatory non-compliance was hypothetical by claiming Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of violations in the future. ¶¶270, 275, 288-89, 295.

These statements were untrue—Defendants knew Mylan had already received multiple Form 483s (including for its critical Morgantown facility) that confirmed the failures had already occurred and were continuing. *See Todd*, 2016 WL 6699284, at *6 n.6 ("representations created an impression that the [] manufacturing facility was in compliance with FDA rules" which "might be deemed deceiving because the FDA observed numerous violations of its regulations"); *Odeh*, 2020 WL 4381924, at *6 ("The [Form 10-Q and 10-K] also referred to receiving a Form 483 from the FDA as a hypothetical issue even though [the company] had, in fact, already received one.").[15]

Defendants' attempts to characterize these statements as truthful are unavailing. First, the argument that the statement "we receive notices" from "time to time" somehow conveyed that Mylan had already received such notices defies logic and the plain language of the disclosure.[16] Notably, the statement does not employ the past tense—we "received"; rather it suggests generally that there are unspecified times when unspecified notices are received—perhaps, now, perhaps never. In any event, "[c]autionary words about future risk cannot insulate from liability the failure

[15] *Twin Master Fund, Ltd. v. Akorn, Inc.*, 2020 WL 564222, at *6 (N.D. Ill. Feb. 5, 2020) (MTD at 33) is misplaced as Plaintiff here does not rely on generic "subject to" regulations misstatements.
[16] Unlike *Lions Gate* (MTD at 31), Defendants did not couch this disclosure in terms of its beliefs about the consequences of pending regulatory action. *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 15 (S.D.N.Y. 2016) ("the Company does not believe . . . the outcome of any currently pending claims . . . will have a material adverse effect on the Company's financial statements")

to disclose that the risk has transpired." *Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004).[17]

Second, Defendants' statements on April 20, 2018—eight days after receipt of the 2018 Form 483—that "we've realized that our Morgantown plant needed to be rightsized" and that this realization was "consistent with discussions we are having with the [FDA]" were similarly misleading because they failed to disclose that Mylan's actions were the direct result of the CGMP and data integrity failures reported by the FDA. ¶290; *Mulligan*, 36 F. Supp. 3d at 961 ("given the pervasive, recurring, and long-standing nature of the alleged problems identified in the FAC, the Court cannot conclude (at this stage) that Defendants' statements regarding the remediation efforts being implemented were not false or misleading when made").

2. Defendants' Statements Regarding Nashik Were Misleading

Defendants additionally misled investors by suggesting that the Nashik regulatory violations were unique to that facility, when they knew of the serious issues plaguing its much larger Morgantown facility. Specifically, after investors learned of the Nashik warning letter on April 3, 2017, Mylan issued a press release on April 11, 2017 downplaying the violations: "The Nashik, India, facility is just one of Mylan's 50 manufacturing sites across the globe." ¶277. Likewise, in investor earnings calls on May 10, 2017, Mr. Malik told investors that Mylan had received the Nashik warning letter and was "working closely with the FDA to respond to and address the issues raised in the letter," while generally noting "shifting inspections by various global regulators across our 50 facilities." ¶279; *see also* ¶286.

[17] Because no reasonable investor would have read Defendants' risk factor as a disclosure of the highly material Form 483s, Defendants reliance on *Carvelli*, 934 F.3d at 1322 (MTD at 32) is misplaced. Moreover, Defendants' general statements that "the pharmaceutical industry is heavily regulated" does not somehow cure the false and misleading disclosures in the risk factors. *In re Innocoll Holdings Pub. Ltd. Co. Sec. Litig.*, 2020 WL 1479128, at *17 (E.D. Pa. Mar. 25, 2020) ("courts have rejected the alleged significance of boilerplate warnings true to every company that interacts with the FDA").

These statements falsely assured investors that Mylan's noncompliance was contained to Nashik when, in reality, the FDA had already discovered more severe and pervasive violations at Morgantown. ¶¶150-51. *See Monk*, 2011 WL 6339824, at *23 (finding actionable statement that FDA noncompliance was a "very specific inspection of one manufacturing plant"); *Freedman v. Saint Jude Med., Inc.*, 4 F. Supp. 3d 1101, 1114 (D. Minn. 2014) (noting "those statements are susceptible to a reasonable inference by a reasonable investor that [the company] had otherwise had no adverse interactions with the FDA over its compliance with cGMP").

C. Defendants' Statements Regarding The Impact Of Morgantown Remediation Were False And Misleading

Defendants made false and misleading statements about the expansive remediation that was undertaken at Morgantown. ¶¶297, 321-23, 325. Unbeknownst to investors, Defendants were forced to halt production at Morgantown to remediate CGMP and data integrity failures after receiving the 2018 Form 483. ¶178. Rather than disclose the underlying conduct and FDA findings, on April 20, 2018, eight days after receiving the 2018 Form 483, Mylan announced it was laying off 15% of its Morgantown employees and "right-sizing" the facility. ¶179. It was not until *Bloomberg* reported on the 2018 Form 483, on June 27, 2018, that investors became aware of its existence or that the Form 483 "could turn into a Warning Letter or even a Consent Decree[.]" ¶¶181-82. The day after *Bloomberg*'s story, however, Defendants misleadingly stated that the 2018 inspection was part of a "regular[]" inspection and that Mylan was "committed to a robust improvement plan." ¶297. This too was misleading. In truth, the inspection was not "regular" but rather was a surprise inspection prompted by an FDA whistleblower, and followed Mylan's history of failing CGMP and data integrity processes. ¶154. Indeed, the FDA inspection team was an unusually large and sophisticated eight-member team. ¶163.

Moreover, in an August 2018 earnings call, Defendants continued to mislead investors

about the true cause of the Morgantown remediation and the present impact on Mylan's high-volume manufacturing. *Invacare*, 2014 WL 4064256, at *7 ("Defendants appreciated the gravity of the FDA's concerns, knew the risks facing the Company, yet downplayed and mischaracterized them in disclosures to the investing public."). Rather than inform investors about the problems that compelled remediation, Defendant Malik downplayed the Morgantown issues by stating that the remediation "was not triggered just by this FDA inspection. It was part of . . . this year's plan actually to right size it." ¶322. This created the false impression that Mylan's remediation was a strategic decision rather than a required action resulting from the FDA's findings. ¶324.

Mr. Parks and Ms. Bresch also misled investors by stating the impact of Morgantown remediation would be "temporary" and that Mylan would sustain profit levels. ¶¶321, 323. These statements concealed that Mylan's high-volume model depended on deficient quality controls—that if sufficiently remedied, would dramatically impact Mylan's profits. *See Murphy v. Precision Castparts Corp.*, 2017 WL 3084274, at *11 (D. Or. June 27, 2017) (statement that issues were "temporary and product demand would quickly return to normal" deemed actionable).[18]

Likewise, Ms. Bresch made similarly misleading statements during the November 5, 2018 earnings call that the "restructuring and remediation" at Morgantown "may have been misunderstood by the investment community" and that it was only a "temporary" decline in supply.

[18] In a footnote, Defendants contend that three statements are immunized by the PSLRA safe harbor. MTD at 44 n.24. This argument fails. First, none of the statements are forward-looking—they relate to "then-existing conditions" that concealed that Mylan's high-volume manufacturing depended on data integrity and CGMP practices that were no longer viable. *Avaya*, 564 F.3d at 255 ("mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present"); *Dr. Reddy's*, 2019 WL 1299673, at *18 (same). Second, Mylan's "cautionary" statement that "the pharmaceutical industry is heavily regulated" is precisely the type of "vague or blanket (boilerplate) disclaimer" insufficient to trigger the safe harbor. *Trump Casinos*, 7 F.3d at 371-72. In fact, "courts have rejected the alleged significance of boilerplate warnings true to every company that interacts with the FDA." *Innocoll*, 2020 WL 1479128, at *17. Third, Plaintiff has alleged Defendants' actual knowledge, nullifying the safe harbor. *See* § III.A.

¶325. This falsely assured investors that Mylan had undertaken the decision voluntarily and not because of the regulatory scrutiny and CGMP failures documented by the FDA. ¶¶326-27. Defendants argue that Mylan's August 2018 and November 2018 press releases disclosed that the remediation impacted business. MTD at 44-46. But these releases mainly conveyed past effects: "these actions have had a significantly negative impact" and "the Company has incurred significant expenses for incremental manufacturing variances, site remediation and restructuring charges." Def. Ex. 26 at 3. The statement that the issues would only "continue through the end of 2018" does not cure the false impression that these issues would only be "temporary."

III. PLAINTIFF ADEQUATELY ALLEGES SCIENTER

A complaint adequately pleads scienter by alleging facts that give rise to a strong inference of either reckless or conscious misbehavior. *See Avaya*, 564 F.3d at 251. A plaintiff need only allege facts that "constitute circumstantial evidence of reckless or conscious misbehavior." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1422. Scienter exists where, as here, Defendants: (i) "engaged in deliberately illegal behavior"; (ii) "knew facts or had access to information suggesting their public statements were not accurate"; or (iii) "failed to check information they had a duty to monitor." *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000).

When assessing whether a complaint raises a strong inference of scienter, a court considers "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets this standard." *Tellabs*, 551 U.S. at 323. The inference "need not be irrefutable, *i.e.*, of the 'smoking-gun' genre[.]" *Id.* at 324. Instead, a "strong" inference is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* Only "plausible opposing inferences"—*i.e.*, plausible nonculpable reasons for defendants' conduct—that may be "rationally drawn from the facts

alleged" may be considered. *Id* at 314, 323. Thus, Defendants must show that the allegations raise an inference of nonculpable conduct that is stronger than an inference of scienter. *Id*. at 335.

As the Third Circuit has explained, the analysis must be "case specific" and "ultimately rest[s] not on the presence or absence of certain types of allegations but on a practical judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as not that defendants acted with scienter." *Avaya*, 564 F.3d at 269. Plaintiff alleges a strong inference of scienter through allegations that: (i) Defendants knew of and had access to information concerning Mylan's CGMP and data integrity violations; (ii) the systemic misconduct constituted violations of federal law, subjecting Mylan to penalties, remediation and business disruption; (iii) the violations were pervasive and occurred at multiple facilities for years; (iv) former employees corroborate that the violations were widely known within Mylan; (v) Morgantown was critical to Mylan's business; and (vi) Defendants were motivated to conceal the truth. *See generally* ¶¶ 222-51. Viewing the mosaic of Plaintiff's allegations "holistically," as required under *Tellabs*, Plaintiff's theory of scienter is at least as cogent and compelling as any non-fraudulent inference.

A. Defendants Had Knowledge Of Facts And Access To Information

Defendants received direct warnings, before and during the Class Period, that Mylan had defective quality controls and widespread CGMP and data integrity violations at Morgantown—facts that belied their public statements. "To adequately plead scienter, it is sufficient for plaintiffs to allege that defendants had knowledge of facts or access to information that contradict[ed] their statements." *In re Cambrex Corp. Sec. Litig.*, 2005 WL 2840336, at *11 (D.N.J. Oct. 27, 2005). "[W]hen the alleged fraud is based on non-disclosure of facts, evidence that the defendants had actual knowledge of the facts is sufficient to show scienter." *Odeh*, 2020 WL 4381924, at *7; *see also Saint Jude Med., Inc.*, 4 F. Supp. 3d at 1122 (scienter alleged where known facts contradicted statements about "regulatory compliance, quality controls, and the safety and reliability").

Actual Knowledge. First, the Nashik Form 483, Nashik warning letter, and the Morgantown 2016 Form 483 informed Defendants of systemic and pervasive CGMP violations at Mylan. ¶¶69, 91-94, 97-106. *Cf. Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014) ("[W]hen the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity."); *In re EQT Corp. Sec. Litig.*, 2020 WL 7059556, at *20 (W.D. Pa. Dec. 2, 2020) (scienter alleged where company touted transaction when it "was actually keenly aware that it was experiencing significant operational and financial issues").

Second, in April 2017, the FDA explicitly told Mr. Malik and six other Mylan executives that it was "stunned" by the "egregious" violations in the 2016 Form 483 and questioned whether Mylan was being "transparent at all of its sites." ¶¶9, 150, 224. Defendants also knew that the FDA rated Morgantown "Official Action Indicated" and drafted a warning letter sanctioning Mylan. ¶152. Indeed, Defendants had actual knowledge that the FDA held off on issuing the letter only because Mr. Malik promised a full remediation at Morgantown. *Id.*; ¶151. Privately, however, Mr. Malik refused to implement the promised remediation, internally demanding that Morgantown increase its annual production goals and slash its regulatory compliance and quality control budget. ¶¶8, 132, 135, 157; *see also* ¶160 (FE8 reporting that Mr. Malik "immediately dismissed" the idea of increasing resources to address 2016 Form 483 at 2017 town hall meeting).

Third, the 2018 Form 483 and 2018 warning letter confirm that Defendants were aware of and did not address the CGMP violations at Morgantown throughout the Class Period. For example, the warning letter stated that: (i) the FDA previously "cited similar CGMP violations at this and other facilities"; (ii) "the unjustified invalidation of failing test results is a repeat violation"; (iii) "[t]hese repeated failures at multiple sites demonstrate that Mylan's management

oversight and control over the manufacture of drugs is inadequate"; (iv) "Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance"; and (v) "Your lack of rigorous oversight of manufacturing changes continues to be a major factor in the unexpected variation observed in your drug products." ¶¶172, 201-03.

Fourth, contrary to Defendants' argument (MTD at 55), Mylan's recall of fifteen drugs due to CGMP failures at Morgantown, including those referenced in the 2016 Form 483, support scienter. ¶¶9, 162, 180, 197, 225; *In re Terravia Holdings, Inc. Sec. Litig.*, 2020 WL 553939, at *7 (N.D. Cal. Feb. 4, 2020) (recalls support scienter); *Able Labs.*, 2008 WL 1967509, *17 (same).

Fifth, Defendants knew that in 2009, the *Pittsburgh Post-Gazette* reported that Mylan evaded FDA's quality regulations by "crash[ing] files" (¶¶119, 228)—the same misconduct cited in the 2017 Nashik warning letter (¶93) and that continued during the Class Period. *See* ¶242. Defendants wrongly contend that a press release issued by Mylan and the *Post-Gazette* as part of a litigation settlement undermines Plaintiff's allegation, MTD at 54, Ex. 30—however, the press release did not retract the reports of Mylan's CGMP violations. Ex. 30.

These direct warnings to Mylan management support a strong inference of scienter. *See, e.g.*, *Able Labs.*, 2008 WL 1967509, at *16-17 (finding scienter where: (i) Form 483 and warning letter "provided notice to the defendants that serious problems existed in the [company's] manufacturing process"; (ii) president's "receipt and review of the FDA warning letter should have alerted him to potential problems"; and (iii) "FDA investigation and Form 483 demonstrate that numerous problems with . . . quality controls continued" after receiving initial warnings).

Unable to challenge Plaintiff's scienter allegations, Defendants argue that the Court must determine, on the pleadings, whether Defendants intended to mislead investors. MTD at 48-49. The Third Circuit rejected this standard in *Semerenko v. Cendant Corp.*, 223 F.3d 165, 176 (3d Cir.

2000), holding "it is irrelevant that the misrepresentations were not made for the purpose or the object of influencing the investment decisions of market participants," because:

> The purpose underlying § 10(b) and Rule 10b-5 is to ensure that investors obtain fair and full disclosure of material facts . . . the Class is not required to establish that the defendants actually envisioned that members of the Class would rely upon the alleged misrepresentations when making their investment decisions.

Id. Accordingly, once Defendants "chose to speak" on topics such as quality control and CGMP, their knowledge of facts belying those statements, i.e., the pervasive CGMP violations, properly alleges scienter. *See Odeh*, 2020 WL 4381924, at *7 (holding that knowledge of CGMP violations and Form 483 was sufficient to plead defendants' scienter for risk disclosure discussing company's "potential" to receive a Form 483); *see also Dr. Reddy's*, 2019 WL 1299673, at *17 (allegations of known Form 483s, warning letters, and CGMP violations sufficient to plead scienter).[19]

Access to Information. Although Plaintiff pleads that Defendants possessed actual knowledge of Mylan's regulatory violations, Defendants' scienter also is supported by their (i) duty to ensure the adequacy of Mylan's quality assurance processes, *see Novak*, 216 F.3d at 311 (scienter alleged where defendants "failed to check information they had a duty to monitor"); and (ii) access to and receipt of information about the deficient state of Mylan's CGMP compliance. *See Vrakas v. U.S. Steel Corp.*, 2018 WL 4680314, at *14-15 (W.D. Pa. Sept. 29, 2018)

[19] Defendants' mostly out-of-circuit cases, *see* MTD at 49, are unavailing as plaintiffs in those cases failed to plead facts supporting scienter. *See, e.g.*, *Abiomed, Inc.*, 778 F.3d at 244 (no scienter for allegedly concealing off-label marketing where defendant voluntarily asked the FDA for guidance as to whether conduct was off-label marketing); *In re Columbia Labs., Inc. Sec. Litig.*, 2013 WL 10914123, *4 (D.N.J. June 11, 2013) (no scienter for allegedly concealing poor test results supporting a New Drug Application, where there was no indication that results jeopardized approval); *Brennan v. Zafgen, Inc*., 853 F.3d 606, 611-12 (1st Cir. 2017) (no scienter for allegedly concealing two adverse events in clinical trial because third-party investigators classified them as "superficial" and company stated such events "may not be disclosed to the public"); *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1065 (N.D. Cal. 2014) (no scienter for allegedly concealing product defect, where company "was investigating the extent of the problem, [and] whether it was responsible for it").

(defendants' "access to a Daily Report of Operations [] and an Operating Efficiency Report" sufficient to plead scienter); *SEB Inv. Mgmt. AB v. Endo Int'l, plc*, 351 F. Supp. 3d 874, 905-07 (E.D. Pa. 2018) (same); *Cambrex*, 2005 WL 2840336, at *11-12 (same); *Lovallo v. Pacira Pharm., Inc.*, 2015 WL 7300492, at *14 (D.N.J. Nov. 18, 2015) (same).

Defendants' had access to negative information, contradicting their public statements:

- FDA regulations required Mylan to thoroughly and contemporaneously document the production process, including all quality testing performed and results obtained. ¶47 (citing 21 C.F.R. §§ 211.100, 212.192); *see generally* ¶¶43-61.

- Mylan adopted a standard operating procedure providing that "Senior Management," together with Mylan's Quality Council, were responsible to "ensure continuing suitability and effectiveness of quality systems" at Mylan. ¶¶173, 229.

- Mylan assured shareholders that it had "global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system [and] Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training." ¶¶230, 292 (Mylan touting "extensive, formal internal-audit program to help monitor activity at our facilities").

- Defendants had access to real-time quality control testing data through Mylan's TrackWise system, which showed: (i) a backlog of unresolved investigations; (ii) repeated invalidation of failing results; (iii) repeated re-testing of failing results without investigation; and (iv) a trend of cross-contamination events. ¶¶125, 127, 231.

Defendants' statements that "senior management" was responsible for "ensuring" CGMP compliance, and that Mylan had processes in place to do so, add to a strong inference that Defendants knew of or recklessly disregarded Mylan's CGMP violations. *Cf. Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Swanson*, 2011 WL 2444675, at *12 (D. Del. June 14, 2011) (finding scienter on basis of "statements by the Defendants themselves about how they 'recorded' sales, [and] 'closely monitor[ed]" information) (brackets in original).

In response, Defendants incorrectly contend that Plaintiff is required, and has failed, to plead (i) details of the specific information to which Defendants had access and (ii) that Defendants

indeed accessed the information. MTD at 51-52. First, Plaintiff details the content of the information to which Defendants had access through, for example, the findings in the Form 483s, the warning letters, and accounts from FEs and *Bottle of Lies*. Second, Defendants publicly represented that they reviewed quality systems data. Third, requiring Plaintiff to detail Defendants' actual review of information to which they had access would amount to a showing of actual knowledge and render the "access to information" standard a nullity.[20] In any event, these allegations add to the Court's holistic *Tellabs* analysis. *Id.*, 551 U.S. at 323.

B. The Nature And Magnitude Of The Misconduct Is Probative Of Scienter

Scienter is further evidenced by the nature of Defendants' misconduct; specifically, violating drug safety regulations to increase production. *See* § II.A; *see also* ¶¶43-61. It is well-established that a strong inference of scienter arises where defendants "engaged in deliberately illegal behavior." *Novak*, 216 F.3d at 311; *see also Aviva Partners LLC v. Exide Techs.*, 2007 WL 789083, at *12 (D.N.J. Mar. 13, 2007) (scienter reinforced by "conscious wrongdoing, such as intentional fraud or other deliberate illegal behavior") *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 385 (S.D.N.Y. 2003) (scienter alleged where defendants "engaged in . . . deliberately illegal behavior" that does "not happen accidentally, negligently, or even recklessly").

First, Mylan is required to comply with federal quality-control regulations, including the prohibition on "testing into compliance." ¶¶43-44 (*citing* 21 C.F.R. Pt. 11, 21, C.F.R. §§ 210, 211, 351); ¶¶46-50. Mylan's breach of these regulations was pervasive: (i) the FDA characterized the violations at Morgantown as "egregious," "stun[ing]," and "significant," ¶233; (ii) the FDA commissioner was so outraged, he published Mylan's Morgantown warning letter on Twitter, ¶235; and (iii) analysts noted the violations were serious and "raise concerns around patient safety

[20] Plaintiff's allegations of knowledge and access to information defeat Defendants' contention that Plaintiff relies on "common knowledge" allegations to plead scienter. MTD at 52-53.

and product quality and thus will require extensive actions to correct." ¶233. This was especially true at Morgantown as Mylan continued to violate FDA regulations after it received the 2016 Form 483 and Mr. Malik assured the FDA that Mylan had "integrity." ¶151. *Cf. Todd*, 2016 WL 6699284, at *12-13 (failure "to correct a deficiency identified in [earlier] Form 483, which appeared again during [later] inspection" supports inference of scienter). Defendants' illegal conduct further distinguishes this case from those involving mismanagement. *See* MTD at 58; *SEC v. Saltzman*, 127 F. Supp. 2d 660, 668 (E.D. Pa. 2000) (rejecting "mere mismanagement" defense where plaintiff "presented facts which, if substantiated, show that [defendant] made material misrepresentations and omissions, with scienter"). As a heavily regulated company, compliance with FDA regulations in its flagship facility is considered a "core operation." *See* § III.E.

Second, the regulatory violations were, themselves, acts of concealment as Mylan falsified and destroyed testing data across multiple facilities, including by shredding documents, ¶103, crashing computers, ¶86, altering drug samples, ¶102, pre-injecting samples, ¶101, and creating a "façade" of documents at Morgantown, ¶¶154-55, 158, bolstering the strong inference of scienter. *See, e.g.*, *In re Eletrobras Sec. Litig.*, 2017 WL 1157138, at *11 (S.D.N.Y. 2017) (inference of scienter where issuer concealed bribes); *In re Galena Biopharma, Inc. Sec. Litig.*, 117 F. Supp. 3d 1145, 1166 (D. Or. 2015) (executive's "alleged attempts to hide" misconduct "also support a strong inference of scienter"); *Nathanson v. Polycom, Inc.*, 87 F. Supp. 3d 966, 979 (N.D. Cal. 2015) ("One does not . . . hide those numerous inappropriate expense claims without intent to defraud.").

Third, the magnitude of sanctions associated with Mylan's CGMP violations supports scienter. *Mulligan*, 36 F. Supp. 3d at 970 ("[G]iven the importance of manufacturing and quality control to the success of Impax and the fact that both areas of operation had been flagged by the FDA, it is a logical, and strong, inference that the defendants were aware of the alleged severe and

pervasive problems in [the] facility."). Mylan's violations risked (i) human safety through release of "adulterated" drugs, ¶52, and (ii) the prospect of FDA enforcement through fines, remedial action, drug recalls, cessation of business operations, and refusal to approve drugs for sale. ¶55; *see also* ¶235 (identifying other drug makers committing similar violations that suffered severe financial issues). Indeed, Morgantown's eventual remediation proved costly: its production fell by two-thirds and Mylan's revenues declined by hundreds of millions of dollars. ¶¶15, 178.

Finally, Mr. Malik, and thus Mylan, were keenly aware of the risks resulting from regulatory violations: during Mr. Malik's tenure at Ranbaxy, the company fabricated data concerning 200 products sold across 40 countries, which led to an FDA investigation, an armed raid on Ranbaxy's headquarters, the issuance of two warning letters, and the ultimate implosion of the company. ¶¶57, 251; *see also Todd*, 2016 WL 6699284, at *12-13 (allegation that defendant had a "long history managing FDA regulated companies" and thus had "a comprehensive understanding of FDA procedures specific to STAAR's industry" supported inference of scienter). Defendants' contention that Mr. Malik's resignation from Ranbaxy reflects an intolerance for non-compliance cannot be credited. MTD at 54. The inference to be drawn from Mr. Malik's tenure at Ranbaxy is that a senior pharmaceutical executive would be aware of pervasive CGMP noncompliance and related risks. Additionally, the whistleblower who prompted the 2016 inspections of Nashik and Morgantown confirmed that former Ranbaxy employees holding "key leadership positions at Mylan" engaged in data fraud "under Rajiv Malik's leadership." ¶85.

C. The Duration Of The Violations Support An Inference Of Scienter

The duration of Mylan's CGMP violations supports a strong inference that Defendants knew about the illegal conduct. It is well-settled that prolonged misconduct contributes to a strong inference of scienter. *See, e.g.*, *In re Rent-Way Sec. Litig.*, 209 F. Supp. 2d 493, 507 (W.D. Pa. 2002) (alleged fraud spanning two years supported strong inference of scienter); *In re Genworth*

Fin. Inc. Sec. Litig., 103 F. Supp. 3d 759, 785 (E.D. Va. 2015) (misrepresentations "over the course of a year also suggests a substantial degree of scienter"); *In re Pall Corp.*, 2009 WL 3111777, at *8 (E.D.N.Y. Sept. 21, 2009) (duration of fraud one factor supporting scienter).

Mylan's CGMP violations and data integrity failures existed at Morgantown before and throughout the three-year Class Period. ¶¶98-120, 155, 164-68, 195-204; *see also Todd*, 2016 WL 6699284, at *13 ("STAAR's alleged history of noncompliance further supports the inference that [CEO and President] kept a close watch on possible violations of FDA regulations."). Additionally, Mylan committed the same CGMP violations across multiple sites, suggesting endemic problems about which management was aware. *Compare* ¶¶92-94 (Nashik violations including "test[ing] into compliance," crashing files, and failure to clean equipment) *with* ¶¶98-104, 118-19 (same violations at Morgantown); *see also* ¶202 (2018 Form 483, referring to CGMP violations at Morgantown as "similar" to "repeat violations at multiple sites," dating back to 2015); *Todd*, 2016 WL 6699284, at *12-13 (strong inference of scienter where FDA alerted company to similar non-compliance in California and Swiss facilities).

D. Internal Knowledge Of The Violations Supports An Inference Of Scienter

Former employee accounts confirm that Mylan's CGMP and data integrity violations were widely known within Mylan, supporting a strong inference that Defendants knew of or recklessly disregarded them. *See generally* ¶¶108-43; *see also Cornwell v. Credit Suisse Grp.*, 689 F. Supp. 2d 629, 637 (S.D.N.Y. 2010) (inferring scienter from allegations of "widespread knowledge at CSG of . . . problems with valuation, risk management and internal controls"). For example:

- FE6 reported that prior to the start of the Class Period, senior Mylan executives, including the Vice President of Operations, the Head of the Morgantown facility, and the Heads of Quality and Manufacturing at Morgantown, discussed that Morgantown could not satisfy its CGMP compliance and product quality obligations. ¶¶133, 240.

- FE1 recalled in 2015 and 2016, reporting Morgantown's failure to test manufactured drugs and equipment, and Mylan's practice of "testing into compliance" to Morgantown's Head of Quality, Kim Kupec, and the Senior Director of Quality Assurance Operations, Eddie Koski, but his warnings were ignored. ¶241.

- FE2 described that, prior to the Class Period until April 2018, testing into compliance was widespread at Morgantown at the express direction of his supervisors in the Quality Assurance division. ¶241. FE4 confirming that "testing into compliance" was "commonplace" at Mylan. *Id.* FE5 confirming testing into compliance was prevalent at Morgantown, Nashik, and Bangalore, India. *Id*. FE5 recalling that Associate Director of Global Compliance told him to falsify records. ¶120.

- FE1 and FE2 confirmed that data manipulation—including "preinjecting" samples and "crashing files"—were widespread throughout Mylan's facilities. ¶242.

- FE1 and FE3 raised, to no avail, cross-contamination issues with their superiors. ¶243.

- FE1, FE3, and FE4 stated that Mylan tested no more than 5 percent of the drugs produced because of the massive production volume flowing through Morgantown. ¶¶121-22, 244. FE4 recalled, and Mylan's Head of Global Quality admitted, that the size of Morgantown's production volume prevented sufficient testing. ¶244.

Similarly, the accounts of FDA whistleblowers further show that the CGMP and data integrity violations were well-known within Morgantown, were directed by Mr. Malik, and could not have been missed by management. *See* ¶¶6, 85-86 (whistleblower informing FDA in September 2015, that Mr. Malik and others in "key leadership positions at Mylan" directed employees at Hyderabad and Morgantown to manipulate test results); *id.* (whistleblower stating that Mr. Malik's team instructed Mylan personnel to crash computers to avoid reporting failing test results); ¶87 (former Mylan chemist stating that data manipulation occurred under Mr. Malik's leadership); ¶88 (Mr. Malik deployed R&D teams to different sites to manage failing data).

Furthermore, in early 2018, a second Morgantown whistleblower privately told the FDA that, instead of remedying problems cited in the 2016 Form 483 as Mr. Malik promised, Mylan was focused on creating a "façade of documents" to fend off the agency and had developed an "embedded culture" of fraud. ¶154. FEs confirm that Mylan implemented superficial remedial

measures at Morgantown. *See* ¶¶155-60. These corroborative FE and FDA whistleblower accounts support a strong inference that Defendants were aware of Mylan's CGMP violations.

Defendants' contention that the allegations attributable to the FEs should be ignored because several FEs did not claim to "have had any interaction with the Individual Defendants" fails. *See* MTD at 17-19, 50-51. First, as detailed above, several of the FEs provide firsthand information on the CGMP violations Mylan management knew and/or directed. Second, Plaintiff relies on the other FE accounts to demonstrate that the CGMP violations were pervasive, and well-known across multiple facilities, such that Defendants could not have missed them. *See In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 433, 505 (S.D.N.Y. 2005) (inferring senior officers' scienter from "widespread internal knowledge" of the material facts underlying the fraud).[21] Third, the information the FEs provide is credible given it is corroborative of other FE accounts, the FDA findings, and the former Mylan employee accounts discussed in *Bottle of Lies*. *See Shah v. Zimmer Biomet Holdings, Inc.*, 348 F. Supp. 3d 821, 844 (N.D. Ind. 2018) (former employee accounts support scienter when "their accounts are partially corroborated by one another, as well as other evidence"). Fourth, Defendants' argument runs counter to the holistic analysis of *Tellabs* and the Third Circuit's holding in *Avaya*. *See id.*, 564 F.3d at 268-69 (rejecting argument that confidential witness reports be ignored because none of them "claimed to have had any connection to or communication with [defendants], or knowledge about the information or records to which [they] had access").

[21] As Plaintiff relies on these FEs to show Defendants could not have missed the misconduct, rather than what each Defendant learned firsthand, *Abiomed*, 778 F.3d at 245, *Martin v. GNC Holdings, Inc.*, 2017 WL 3974002, at *17 (W.D. Pa. Sept. 8, 2017), and *National Junior Baseball League v. PharmaNet Development Group Inc.*, 720 F. Supp. 2d 517, 555 (D.N.J. 2010), (MTD at 50-51), are misplaced.

E. The Importance Of Morgantown Supports A Strong Inference Of Scienter

As Mylan's flagship facility in the U.S., Morgantown constitutes a "core operation" that Mylan management is presumed to know during the Class Period. "[U]nder the core operations doctrine, misstatements and omissions made on core matters of central importance to the company and its high-level executives gives rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." *In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 653-54 (E.D. Pa. 2015); *see also Avaya*, 564 F.3d at 271; *In re Toronto-Dominion Bank Sec. Litig.*, 2018 WL 6381882, at *14 (D.N.J. Dec. 6, 2018) ("Plaintiffs have alleged the importance of the Canadian retail segment and Individual Defendants['] position within TD Bank, which is enough to allow the core operations doctrine pleading to survive a motion to dismiss."); *Odeh*, 2020 WL 4381924, at *8 ("The Data Integrity Breach and Form 483 issues therefore concerned core matters of central importance to a company."); *Dr. Reddy's*, 2019 WL 1299673, at *16 (statements "ensuring compliance with safety and manufacturing quality standards" concerned a core operation, giving rise to a strong inference of scienter); *In re Enzymotec Sec. Litig.*, 2015 WL 8784065, at *18 (D.N.J. Dec. 15, 2015) (scienter inferred where "matter at issue" was "central to the core business of the Company").

Morgantown was critical to Mylan and manufactured approximately 85% of the oral solid doses, 17 billion, that Mylan sold in the US. ¶¶7, 34, 247. Mylan designated Morgantown as a "significant" facility in its Form 10-Ks. ¶¶247, 267. Mr. Malik publicly stated that Morgantown was "significant" to Mylan. ¶247. The importance of Morgantown was evidenced further when it was compelled to remediate—revenue declined $2.8 billion (22 percent) and net sales fell 18 percent in 2018 "primarily driven by" the remediation at Morgantown. ¶¶186, 207, 217. Ultimately, Morgantown was forced to halt production and reduce its generics portfolio by nearly two thirds. ¶83; *see also Carmignac Gestion, S.A. v. Perrigo Co. plc*, 2019 WL 3451523, at *16

(D.N.J. July 31, 2019) ("Allegations that fraud related to a high-earning segment of a company have been found sufficient to support a core operations inference."); *Hospira*, 2013 WL 566805, at *27 (scienter inferred where FDA regulatory failures related to "largest" "crown jewel" facility).

It is "exceedingly unlikely" that Ms. Bresch, Mr. Malik, and Mr. Park—Mylan's CEO, President, and CFO, respectively—were "unaware of" (i) the widespread data manipulation and CGMP violations at Morgantown, and (ii) the serious financial and operational risks associated with the violations if left unremediated. *Hospira*, 2013 WL 566805, at *27; *see also Avaya*, 564 F.3d at 269-70 (position as "corporate officer" one factor considered in scienter analysis); *Feinberg v. Benton*, 2007 WL 4355408, at *6 (E.D. Pa. Dec. 3, 2007) ("a court may factor in the position of the defendant as circumstantial evidence when the information is of great importance"); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *17 (D.N.J. Aug. 28, 2017) (same). Indeed, "it is 'absurd' to think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged substandard, non-compliant conditions pervading [its] manufacturing and quality control divisions—the heart of a company whose main business is manufacturing pharmaceuticals for public consumption." *Mulligan*, 36 F. Supp. 3d at 970. And the "idea that the defendants here would be unaware of these manufacturing and quality control problems is even more unlikely given the repeated Form 483s and the Warning Letter from the FDA." *Id.*

Defendants' reliance on *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 155 (3d Cir. 2018) to attack the core operations inference, MTD at 53, is misplaced. *GNC* involved unapproved ingredients in a small subset of dietary supplements—hardly a core operation. Accordingly, the court held that the plaintiffs could not rely on the core operation doctrine without also alleging "specific information conveyed to management and related to the fraud," which they did not do.

Id. In contrast, Plaintiff alleges that Morgantown was a key facility for Mylan, and, as detailed above, that Defendants knew of or recklessly disregarded Mylan's pervasive CGMP violations.

F. Defendants Were Motivated To Conceal The Truth

Contrary to Defendants' contention, MTD at 58-59, a plaintiff need not allege a culpable motive to plead a strong inference of scienter. *See, e.g.*, *Tellabs*, 551 U.S. at 325; *Tomaszewski*, 482 F. Supp. 3d at 334 ("motive allegations" are not necessary to support an inference of scienter). But, here, Plaintiff does allege that Mylan was experiencing pricing pressure, which caused Mylan to (i) drop its prices, (ii) realize narrower margins, and (iii) rely on increased sales volume to generate income, possible only by noncompliant manufacturing processes. ¶¶62-65.

Defendants also were motivated to hide misconduct at Morgantown as they knew remediation would be costly, reduce production, and signal that CGMP violations were not isolated to Nashik. *See* ¶¶148, 153. Defendants also kept quiet because they could not afford another setback after facing criticism over: (i) allegations of Medicare fraud and antitrust violations; (ii) outsized executive compensation (including a $100 million director payout); (iii) high-profile acts of dishonesty by leadership (including Ms. Bresch's misstatements about academic qualifications); and (iv) the composition of Mylan's Board, which included Ms. Bresch and Mr. Malik. ¶149.

G. Plaintiff Alleges Corporate Scienter For Mylan

Because Plaintiff alleges scienter for each Defendant and other high-ranking Mylan executives, *see, e.g.*, ¶¶240-44 (identifying senior executives with knowledge of CGMP violations), scienter is properly imputed to Mylan. Defendants' assertion that Mylan's scienter can derive only from the Individual Defendants' scienter (MTD at 47 n.26) misstates the law. As many courts have recognized, a corporate defendant's scienter is adequately alleged "where the pleaded facts create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter," including management-level executives, whether or not they are

named defendants. *Sun v. Han*, 2015 WL 9304542, at *12 (D.N.J. Dec. 21, 2015) (corporate scienter pled through unnamed senior auditors) (quoting *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008)); *see also In re Cognizant Tech. Sols. Corp. Sec. Litig.*, 2018 WL 3772675, at *33-34 (D.N.J. Aug. 8, 2018) (non-defendant officer's scienter imputed to corporate defendant); *In re NUI Sec. Litig.*, 314 F. Supp. 2d 388, 412-13 (D.N.J. 2004) (company's scienter pled through non-defendant assistant general counsel).[22]

H. Defendants' Inference Is Not More Compelling

Finally, the inference of scienter here is at least as compelling as any nonculpable inference. MTD at 48, 55-58. Critically, Defendants' assertion that the decision on whether and when to disclose a Form 483 is discretionary mischaracterizes the Complaint. *See Initial Public Offering*, 241 F. Supp. 2d at 332-33 (rejecting defendants' efforts to "rewri[te] the Complaints in a way that they believe favors dismissal"). This case is about misrepresenting and concealing pervasive violations of mandatory FDA regulations—not simply the disclosure of any particular Form 483.

Regardless, Defendants' proposed counter-inferences are implausible. For example, Defendants argue that it is "entirely plausible and reasonable that Mylan did not disclose the 2016 Form 483 because it believed it could address the FDA's concerns." MTD at 56. In support,

[22] Defendants' reliance on *Rahman v. Kid Brands, Inc*., 736 F.3d 237, 246 (3d Cir. 2013) (MTD at 47 n.26), is misplaced and ignores numerous decisions within this Circuit. *Rahman* merely noted that the Third Circuit has "neither ha[s] accepted nor rejected" the Seventh Circuit's approach to corporate scienter, whereby a corporation's scienter can be inferred from the widespread nature of the fraud, notwithstanding the plaintiff's inability to identify any particular corporate agent with scienter (either a named defendant or a senior company officer). *Id*. Courts within this Circuit, however, have held that corporate scienter may derive from the scienter of unnamed corporate agents. *See, e.g.*, *Cognizant*, 2018 WL 3772675, at *34 ("There is a strong inference that someone involved with the making of the 10-K and the Sustainability Reports knew of their falsity."); *In re Merck & Co. Sec., Derivative & ERISA Litig.*, 2013 WL 396117, at *14 (D.N.J. Jan. 30, 2013) ("Defendants have provided no binding authority holding that a corporation's liability under § 10(b) for its alleged false statements and omissions is circumscribed by the imputed scienter of identifiable corporate agents."). In any event, the Complaint here does identify particular Mylan agents, including the Individual Defendants, who knew or recklessly disregarded the truth.

Defendants contend that the "2016 Form 483 raised observations that did not meet the threshold of regulatory significance." *Id.* But this cannot plausibly be drawn from the alleged facts, including: (i) Mylan violated FDA regulations as early as 2009 and throughout the Class Period, *e.g.*, ¶119; (ii) Mylan created a "façade of documents" to hide its regulatory failings rather than remediate Morgantown, ¶154; (iii) Mr. Malik rejected pleas to remediate, choosing instead to slash Morgantown's control budget, ¶¶135, 157; and (iv) shortly after the FDA issued the 2016 Form 483, it rated Morgantown "Official Action Indicated" and was prepared to issue a formal warning letter. ¶152. The FDA held off only because Mr. Malik promised a full remediation. ¶¶151-52. Thus, Defendants' proffered inference is unreasonable and supporting case law is inapposite. *See*, *e.g.*, *Schaeffer*, 2020 WL 7701463, at *13 (holding that delayed disclosure of Form 483 could be based on belief that violations could be remedied, but noting where, as here, "a pattern of FDA feedback reflecting the same unresolved concerns might demonstrate defendants' failure to mention the form was unreasonable").

Likewise, Defendants' contention that it deserves a favorable inference for disclosing some information following the 2018 Form 483, MTD at 57, fails because those disclosures were misleading. Defendants did not mention the Form 483 until after *Bloomberg* reported it and Mylan was engaged in damage control. ¶¶178-85. Moreover, Defendants continued to conceal that the violations had been ongoing for years and that Mylan had: (i) halted production to implement remediation; (ii) cut production by two-thirds; and (iii) recalled multiple drugs. ¶¶178-80. Furthermore, when Defendants disclosed the Morgantown remediation on August 8, 2018, they misleadingly stated that it had been planned and would be "temporary." ¶¶186-87.[23]

[23] Given Defendants' long-standing knowledge of Mylan's misconduct, Defendants' cases are inapposite. *See, e.g.*, *NVIDIA*, 768 F.3d at 1056 (no scienter because defendants "disclosed the

IV. PLAINTIFF ALLEGES CLAIMS UNDER RULE 10b-5(a) AND (c)

Defendants' Motion fails to challenge Plaintiff's separate claims under Rule 10b-5(a) and (c) for engaging in "acts, practices, and a course of business which operated as a fraud and deceit upon [investors]." ¶346. These conduct-based claims "are viewed as distinct from claims under subsection (b) because the former 'make deceptive conduct actionable, as opposed to . . . deceptive statements.'" *Cognizant*, 2018 WL 3772675, at *16-19 (explaining contours of "scheme liability" and collecting cases); *see also Able Labs.*, 2008 WL 1967509, at *14-17 (finding that "[p]laintiff has pled with specificity conduct and participation in a deceptive scheme"). Plaintiff here pleads numerous facts regarding each Defendant's acts in furtherance of Mylan's deceptive course of conduct. *See, e.g.*, ¶¶42, 66-77, 87-88, 121, 129, 132, 150, 186-87, 200. Defendants' failure to even address this claim warrants denial of their motion. *Ga. Firefighters' Pension Fund v. Anadarko Petroleum Corp.*, 2021 WL 182316, at *4-5 (S.D. Tex. Jan. 19, 2021) (noting "Defendants did not move to dismiss" scheme liability and "deceptive business practices" claims based on the defendants' "course of conduct to conceal adverse material information.").

CONCLUSION

Plaintiff respectfully requests that Defendants' Motion be dismissed in its entirety.[24] If the Court dismisses the Complaint in any respect, Plaintiff respectfully requests leave to amend.

Dated: March 16, 2021

Respectfully submitted,

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problem to investors"); *Genzyme*, 754 F.3d at 41 (no obligation to disclose Form 483 where FDA provided comfort that approval timeline was not affected by it).

[24] Because Plaintiff adequately alleges a Section 10(b) claim, dismissal of the Section 20(a) claim also must be denied. The Individual Defendants do not dispute they controlled Mylan, and while "the Third Circuit does not require that culpable participation be pled," Plaintiff pleads their culpable participation in Mylan's violations. *Able Labs.*, 2008 WL 1967509, at *29.

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CERTIFICATE OF SERVICE

I, Andrew L. Zivitz, herby certify that on March 16, 2021, I caused a true and correct copy of the foregoing to be filed electronically with the Clerk of the Court using the CM/ECF system. Notice of this filing will be sent to counsel of record by operation of the Court's CM/ECF automated filing system.

/s/ Andrew L. Zivitz
Andrew L. Zivitz